Supreme Court, U.S.
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No. 03-

IN THE

Supreme Court of the United States

WALGREEN CO., ECKERD CORPORATION, THE KROGER CO., ALBERTSON'S, INC., STOP & SHOP SUPERMARKET CO., HY-VEE, INC., CVS MERIDIAN, INC. and RITE AID CORP.,

Petitioners,

v.

ABBOTT LABORATORIES and GENEVA PHARMACEUTICALS, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In Case No. 03-779, petitioner Andrx Pharmaceuticals, Inc. has asked the Court to grant certiorari to resolve a perceived conflict between the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), and the Eleventh Circuit's decision in this case. The Court has invited the Solicitor General to file a brief expressing the views of the United States in that case. The question presented is whether it is *per se* unlawful under section 1 of the Sherman Act for a pharmaceutical patentee to pay a competitor tens of millions of dollars to keep the competitor's FDA-approved generic drug off the market during the pendency of patent litigation between the patentee and the competitor.

PARTIES TO THE PROCEEDING

In addition to the parties named in the caption, the following are parties to the proceeding in the Court of Appeals:

Louisiana Wholesale Drug Co.

Valley Drug Co.

CORPORATE DISCLOSURE STATEMENT

Petitioner Eckerd Corp. is a wholly owned subsidiary of J.C. Penney Co., Inc.

Petitioner The Stop & Shop Supermarket C. is a wholly owned subsidiary of Ahold USA, Inc.

Petitioner CVS Meridian, Inc. is a wholly owned subsidiary of CVS Corporation.

Petitioners The Kroger Co., Walgreen Co., Albertson's, Inc., Hy-Vee, Inc. and Rite Aid Corporation have no parent corporations and there are no publicly traded companies that own 10% or more of their stock.

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STATEMENT OF JURISDICTION

The judgment of the Court of Appeals was entered on November 18, 2003 upon denial of a timely petition for rehearing. Pet. App. 67a-68a. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 1 of the Sherman Antitrust Act, 15 U.S.C. 1; portions of 21 U.S.C. § 355; and portions of 35 U.S.C. § 271(e) are reproduced at Pet. App. 69a-76a.

STATEMENT OF THE CASE

1. Petitioners are respondents in *Andrx Pharmaceuticals, Inc. v. The Kroger Co. et al.*, Case No. 03-779 in this Court. The petitioner in that case, Andrx Pharmaceuticals, Inc. ("Andrx"), based its petition for certiorari on a perceived conflict between the Sixth Circuit's decision in that case, *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), and the Eleventh Circuit's decision in this case. On January 26, 2004, this Court entered an order inviting the Solicitor General to file a brief expressing the views of the United States regarding the *Cardizem CD* case.

For the reasons expressed in Petitioners' Brief in Opposition in Case No. 03-779, Petitioners do not believe that either the *Cardizem CD* case or this case falls within the exceedingly narrow class of cases that warrant Supreme Court review. We therefore urge the Court to deny certiorari in both cases. However, if the Court were to grant certiorari in *Cardizem CD*, it should also grant certiorari in this case. The issue in both cases is the same.[1] The only material difference is that the Sixth Circuit reached the right result and the Eleventh Circuit did not.

2. This case arises in the context of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Amendments or the Hatch-Waxman Act. Congress' principal purpose in enacting Hatch-Waxman was "to bring generic drugs onto the market as rapidly as possible." *Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

The Hatch-Waxman Act permits generic drug manufacturers to file an Abbreviated New Drug Application (ANDA) rather than a New Drug Application (NDA) when a

1. The patent dispute between Andrx and Hoechst Marion Roussel, Inc. (now known as Aventis Pharmaceuticals, Inc.) centered primarily around issues of infringement rather than validity. In this case, the patent dispute between Abbott Laboratories and its generic competitors concerned validity rather than infringement. In addition, the patent dispute in the *Cardizem CD* case was never resolved while the patent dispute in this case was resolved adversely to the patent holder at both the district court and Federal Circuit levels. While these are potential means of distinguishing the two cases, Petitioners do not believe that the rule of antitrust law governing these cases should turn on the nature of the underlying patent dispute or on whether the dispute was resolved.

brand-name drug has already been approved by the FDA and the generic manufacturer seeks to market a bioequivalent version of that drug. The Act also contains several provisions relating to potential patent disputes between brand-name manufacturers and their generic competitors. Brand-name companies are required to submit to the FDA for listing in the FDA's "Orange Book" patents they own that claim the drug or a method of using the drug for which they have received FDA approval. 21 U.S.C. § 355(b)(1). When a generic manufacturer files an ANDA, it is required to submit one of four possible certifications with respect to patents listed by the NDA holder. One of those certifications, known as a "paragraph IV" certification, asserts that the listed patent is either invalid or will not be infringed by the proposed generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Such certifications (and the resulting litigation) have become more common as brand-name manufacturers obtain and list weak or narrow patents in an effort to extend their patent protection after patents on the chemical compound itself have expired. *See* FTC, *Generic Drug Entry Prior to Patent Expiration* 13-14 (2002) (available at *www.ftc.gov/os2002/genericdrugstudy.pdf*) (noting that brand-name companies sued the first generic applicant in nearly 75% of the cases studied by the FTC and that the generic prevailed in 73% of those cases).

If the generic applicant files a paragraph IV certification and the brand-name company sues the generic applicant within 45 days, the FDA is prohibited from granting final approval to the generic applicant for up to 30 months or until the infringement action is resolved, whichever comes first. 21 U.S.C. § 355(j)(5)(B)(iii). This automatic stay takes effect regardless of the merit of the patent holder's case. For a drug like Hytrin, which had sales of roughly $500 million in the United States prior to generic entry, 2 ½ years of additional

monopoly profits is worth hundreds of millions (if not billions) of dollars. Moreover, since the first-filing generic is entitled to 180 days of generic exclusivity before the FDA can approve additional generics, 21 U.S.C. § 355(j)(5)(B)(iv),[2] keeping the first generic applicant off the market also has the effect of preventing the entry of later-filing applicants. These two provisions create an enormous incentive for brand-name companies to file infringement actions under Hatch-Waxman even if they have no realistic expectation of winning the case.

3. Abbott Laboratories ("Abbott") manufactures and sells Hytrin, a drug used to treat hypertension and benign prostatic hyperlasia (enlarged prostate). The active ingredient in Hytrin is dihydrate terazosin hydrochloride. Terazosin hydrochloride also exists in several anhydrous forms that are bioequivalent to the dihydrate form. Abbott owned broad patents on terazosin hydrochloride that expired in 1994 and 1995, and a patent on the dihydrate form that expired in 2000.

Beginning in 1993, generic manufacturers such as Geneva Pharmaceuticals, Inc. ("Geneva") and Zenith Goldline Pharmaceuticals, Inc. ("Zenith") began filing ANDAs seeking approval to market generic versions of

2. Prior to 1998, the FDA required the generic applicant to be sued by the patent holder and to "successfully defend" that action before it was awarded exclusivity. (This regulation is the reason that Abbott Laboratories had to pay two generic applicants in order to protect itself from competition rather than only one.) The regulation was challenged and, in April 1998, the Court of Appeals for the District of Columbia Circuit held that the FDA's regulation was inconsistent with the statute. *See Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998). The regulation was later amended to delete the "successful defense" requirement.

Hytrin upon expiration of Abbott's broad patents on terazosin. These generic manufacturers used anhydrous teraozosin rather than dihydrate terazosin as their active ingredient in order to avoid Abbott's dihydrate patent. Abbott nevertheless filed suit against each such manufacturer under 35 U.S.C. § 271(e)(2)(A), thereby preventing the FDA from approving the applications for up to 30 months. All told, Abbott filed 17 patent infringement cases against generic competitors relating to Hytrin between 1993 and 1998. It did not win a single case.

In 1996, Abbott was granted a patent on Form IV terazosin hydrochloride, one of several anhydrous forms of the drug (and a form never marketed by Abbott). At that time, Form IV terazosin had been on sale in the United States since the early 1990's and had been purchased by both Geneva and Zenith for use in preparing their ANDAs. Abbott immediately listed the Form IV patent in the FDA's Orange Book, Geneva filed paragraph IV certifications with respect to that patent and Abbott filed a Hatch-Waxman patent infringement case against Geneva relating to Geneva's ANDA for generic Hytrin *tablets*. It did not, however, file a similar case against Geneva relating to Geneva's ANDA for generic Hytrin *capsules*. It also did not file a similar case against Zenith because Zenith refused to file any certification with respect to Abbott's Form IV patent on the ground that the patent did not claim Hytrin or a method of its use and therefore was not properly listed in the Orange Book. Thus, between 1996 and 1998, there was no 30-month stay in effect against Geneva (with respect to its capsule ANDA) or against Zenith.

On March 30, 1998, Geneva received final FDA approval for its terazosin capsule product. Geneva immediately

contacted Abbott, informed Abbott that it had received FDA approval and threatened to launch its capsule "by the end of the week" unless Abbott paid Geneva not to do so. Two days later, on April 1, 1998, Abbott and Geneva entered into one of the two agreements at issue in this case. One day earlier, on March 31, 1998, Abbott and Zenith entered into the other agreement at issue in the case.

Under its agreement with Geneva, Abbott agreed to pay Geneva $4.5 million per month in exchange for Geneva's promise not to "sell, offer for sale, donate, or otherwise distribute in the United States any Terazosin Hydrochloride Product. . . ." Pet. App. 84a. Under its agreement with Zenith, Abbott agreed to pay Zenith $6 million per quarter ($2 million per month) in exchange for a similar promise from Zenith. Pet. App. 98a. In the event that Geneva was awarded an exclusivity period under Hatch-Waxman, the amount to be paid to Zenith during that period was reduced to $3 million per quarter. The Geneva agreement was to terminate upon denial of certiorari in the Form IV patent case relating to Geneva's tablet ANDA or upon entry of another generic. Pet. App. 84a. The Zenith agreement was to terminate upon entry of another generic. Pet. App. 98a.

Geneva did not enter the market with its FDA-approved generic capsule product in April, May, June, July or August of 1998. It did not enter after the district court hearing the Form IV patent case granted summary judgment to Geneva and held Abbott's patent invalid on September 1, 1998. *See Abbott Labs. v. Geneva Pharm., Inc.*, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998). It did not enter after the Federal Circuit affirmed that ruling on July 1, 1999. *See Abbott Labs. v. Geneva Pharm., Inc.*, 182 F.3d 1315 (Fed. Cir. 1999). Geneva finally entered the market on August 13, 1999 after

repurchasing for tens of millions of dollars its right to compete with Abbott prior to this Court's denial of certiorari in the Form IV patent case.

REASONS FOR GRANTING THE PETITION

The Court should not grant this petition unless it also decides to grant Andrx's petition in Case No. 03-779. In the event that the Court grants Andrx's petition, the same factors that led the Court to do so also apply here.

I. If the Court Grants Andrx's Petition in Order to Resolve the Conflict Between the Sixth and Eleventh Circuits, It Should Grant This Petition for the Same Reason.

In its petition in Case No. 03-779, Andrx argued that the Court should grant certiorari to resolve the conflict between the Sixth Circuit's decision in the *Cardizem CD* case and the Eleventh Circuit's decision in this case. In the *Cardizem CD* case, the Sixth Circuit held that an agreement whereby a brand-name drug company pays a generic competitor not to sell its generic product for some period of time is a "plain vanilla horizontal agreement to restrain trade" and a *per se* violation of the antitrust laws. *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 914 (6th Cir. 2003). In this case, the Eleventh Circuit held that application of the *per se* rule to such an agreement is "premature" and must await an analysis of "the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime." Pet. App. 21a, 36a. *See also* Pet. App. 36a n.27 (district court must undertake "an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects").

This is the very case that, according to Andrx, creates a split in the Circuits on the application of the *per se* rule to agreements involving "exit payments" by a pharmaceutical patentee to a generic competitor. It would be anomalous for the Court to conclude that this split requires resolution by the Court while at the same time allowing the Eleventh Circuit's decision on that very issue to go unreviewed. Accordingly, if the Court determines that Andrx's petition in Case No. 03-779 should be granted, it should grant this Petition as well.

II. If the Court Grants Andrx's Petition, It Should Not Allow The Eleventh Circuit's Decision to Stand.

As between the Sixth Circuit's decision in *Cardizem CD* and the Eleventh Circuit's decision in this case, only the Sixth Circuit's decision is consistent with this Court's precedents and with the purposes and policies underlying both the antitrust laws and the patent laws. Therefore, it would be especially anomalous for the Court to grant certiorari in the *Cardizem CD* case and allow the Eleventh Circuit's decision to stand.

The Eleventh Circuit held that application of the *per se* rule to the agreements at issue in this case was premature because Abbott owned a patent on Form IV terazosin. The Court of Appeals reasoned that, if the Form IV patent gave Abbott "a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit." Pet. App. 32a. Contrary to the reasoning of the Court of Appeals, it is in fact perfectly obvious that a patent holder would not pay its potential competitors millions of dollars per month to purchase protection from competition to which

it was already legally entitled and which it could obtain at no more cost than its legal fees. Abbott did not pay tens of millions of dollars to buy something it could get for nothing. Abbott's willingness to make large cash payments, particularly when coupled with the subsequent invalidation of the patent, establish conclusively that the protection from competition that Abbott purchased from Zenith and Geneva exceeded the "lawful degree" of protection which it was capable of obtaining from a federal court as the owner of the Form IV patent.

A. The Eleventh Circuit's Decision is Based on a Misunderstanding of Abbott's Patent Rights.

This Court long ago set out the proper antitrust analysis for cases involving patents. First, the court must examine the applicable patent law in order to determine the precise nature and scope of the exclusionary right granted by Congress. Second, if the challenged restraint exceeds the exclusionary power arising from those patent rights, then ordinary rules of antitrust law govern, and the court's decision to apply the *per se* rule or the rule of reason is determined, as in all other cases, by the nature of the restraint. *See United States v. Line Material Co.*, 333 U.S. 287 (1948); *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942); *United States v. Masonite Corp.*, 316 U.S. 265 (1942).

The Eleventh Circuit reached the wrong antitrust conclusion because it failed to perform the crucial first step of understanding and delineating the nature and scope of Abbott's legal rights as the owner of the Form IV patent. Instead, the Court of Appeals relied on the premise that "[a] patent grants its owner the lawful right to exclude others." Pet. App. 21a. This is accurate as a statement of

patent law only if two additional adjectives are added: ***valid*** patents give their owners the lawful right to exclude ***infringing*** others. Patent holders do not have an absolute right to exclude potential competitors simply because they *claim* to have a valid patent and *claim* that the competitor's product infringes the patent. Yet that is precisely what Abbott obtained through these agreements: an absolute right to exclude both Geneva and Zenith for the duration of the agreements based simply on Abbott's *claim*—which both competitors denied—that it had a "lawful right" to exclude the proposed generic products of those two competitors. An absolute and unconditional right to exclude necessarily exceeds a qualified and conditional one. In the words of Professor Hovenkamp, a leading antitrust authority whose treatise was repeatedly cited by the Court of Appeals, Abbott purchased "a guaranteed insulation from competition, without the risk that the patent is held invalid. [Patent] policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors." Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1761-62 (2003).

In addition to disregarding basic patent law, the Court of Appeals also disregarded explicit congressional direction regarding pretrial competition between pharmaceutical patentees and generic competitors. In the Hatch-Waxman Act, Congress granted to holders of pharmaceutical patents 30 months of guaranteed exclusion pending resolution of a lawsuit initiated by the patent holder. This automatic exclusion—which in original versions of the legislation was for only 18 months—was part of Congress' complex balancing of the rights of patent holders and those of consumers and generic manufacturers. *See* Engelberg, *Special*

Patent Protection Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?, 39 IDEA 389, 398-407 (1999) (reviewing legislative history). Congress withheld automatic exclusion when the patent holder failed to follow the statutory procedure or when the 30 months expired. It is undisputed that Abbott did not qualify for automatic pretrial exclusion as to either Geneva (with respect to capsules) or Zenith under Hatch-Waxman. Yet Abbott has been allowed to purchase the automatic right of exclusion that Congress deliberately withheld and then use nonexistent statutory "rights" as a defense to antitrust liability.

Had the Eleventh Circuit conducted the careful analysis of patent law that this Court requires, it would have been obvious that the Court of Appeals' premise was false: Abbott's right to exclude was conditional, not absolute. Under the actual rules specified by Congress, there was only *some probability* that Abbott would be able to obtain pretrial exclusion of the generic products by obtaining a preliminary injunction from the district court. The Court of Appeals thus erred in assigning *absolute* exclusionary power to Abbott's patent for purposes of antitrust analysis. If Abbott had absolute exclusionary power, as the Eleventh Circuit assumed, it would not have had to pay Zenith and Geneva to stay off the market.

In enacting the patent laws and Hatch-Waxman, Congress struck a balance between the nation's interest in encouraging innovation through protection of intellectual property rights and the equally important societal interest in competition. As this Court put it in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989), the constitution and statutes of this country embody an understanding that "free exploitation of ideas will be the rule, to which the

protection of a federal patent is the exception." By allowing Abbott to purchase from its competitors protection from competition that Congress deliberately withheld, the Court of Appeals has improperly substituted its judgment as to the proper balance between innovation and competition for that of Congress and this Court.

B. The Eleventh Circuit's Decision Improperly Allows Abbott to Obtain Monopoly Privileges in an Unpatentable Invention.

In addition to misunderstanding the nature of Abbott's patent rights, the Eleventh Circuit disregarded clear precedent of this Court that precludes Abbott from relying on an invalid patent as a defense to antitrust liability. Contrary to the Court of Appeals' decision, the *Walker Process* case[3] is not "[t]he only time" this Court has addressed the circumstances under which a monopolist's claimed patent rights do not shield it from antitrust liability. Pet. App. 26a. Indeed, the Court's decision in *Walker Process* dealt with *Noerr-Pennington* immunity for seeking judicial enforcement of a patent, not what the Eleventh Circuit referred to as patent immunity, and *Noerr-Pennington* immunity is not an issue in this appeal. Pet. App. 16a n.14.

This Court has emphasized repeatedly that "[t]he federal patent system . . . embodies a carefully crafted bargain for encouraging the creation and disclosure of *new, useful, and nonobvious* advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats*, 489 U.S. at 150-51 (emphasis supplied).

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3. *Walker Process Equip., Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

Form IV terazosin was not "new" and therefore not patentable. Under federal patent law, inventors of unpatentable inventions do not obtain the "exclusive right to practice the invention for a period of years." Yet the Eleventh Circuit's decision allows Abbott to obtain exactly such a right through private agreement and then to interpose its invalid patent as a defense to antitrust liability. The decision thus allows Abbott to obtain indirectly what it may not obtain directly.

This holding by the Eleventh Circuit is contrary to longstanding precedent of this Court. The Court has long recognized that an invalid patent may not be used as a defense to antitrust liability under section 1 of the Sherman Act. *See United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57 (1973) (in light of the strong "public interest in enjoining violations of the Sherman Act, the United States is entitled to attack the validity of patents relied upon to justify anticompetitive conduct otherwise violative of the law"). *Glaxo* relied on a line of cases which permitted patent licensees to prove patent invalidity to defeat their contractual obligation to pay royalties in cases where the licensee alleges conduct that would otherwise violate the antitrust laws.[4] *See MacGregor v. Western Elec. & Mfg. Co.*, 329 U.S. 402 (1947); *Edward Katzinger Co. v. Chicago Met. Mfg. Co.*, 329 U.S. 394 (1947); *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942). In *Sola*, for example, the question before the Court was whether a licensee could "challenge a price-fixing

4. These cases predate *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), which held that "an invalid patent [is] so serious a threat to the free use of ideas already in the public domain" that licensees should be able to prove invalidity whether or not they allege an antitrust violation. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 488-89 (1974).

clause in the [license] agreement by showing that the patent is invalid, and that the price restriction is accordingly unlawful because not protected by the patent monopoly." 317 U.S. at 173. This Court held that an antitrust violation could be proven by "proof of the invalidity of the patent." *Id.* at 177. The Eleventh Circuit has now held otherwise.

The Eleventh Circuit's decision is also inconsistent with this Court's decision in *Bonito Boats*. In *Bonito Boats*, this Court held that the standards of novelty, usefulness and nonobviousness in the patent laws "express a congressional determination that the creation of a monopoly in [unpatentable] information would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use." 489 U.S. at 148. The Court therefore struck down a Florida statute that gave patent-like protection to inventions that, like Abbott's invention of Form IV terazosin, did not qualify for such protection under federal patent law. Under the current state of the law to be applied by federal judges sitting in Florida, the State of Florida is precluded from granting monopoly privileges to Abbott in connection with Form IV terazosin, but profit-seeking private parties are free to buy those same privileges from their competitors with impunity. This result is not merely bad antitrust law, but bad patent law as well.

CONCLUSION

If the Court grants certiorari in Case No. 03-779, it should grant certiorari in this case as well. If it denies certiorari in that case, it should also deny this Petition.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT DATED AND FILED SEPTEMBER 15, 2003

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 02-12091

D.C. Docket No. 99-01317-MD-PAS

VALLEY DRUG COMPANY,
LOUISIANA WHOLESALE DRUG COMPANY, INC., et al.,

Plaintiffs-Appellees,

v.

GENEVA PHARMACEUTICALS, INC.,
ABBOTT LABORATORIES,

Defendants-Appellants.

Appeal from the United States District Court for the Southern District of Florida

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(September 15, 2003)

Before TJOFLAT and ANDERSON, Circuit Judges, and STAFFORD*, District Judge.

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* Honorable William H. Stafford, United States District Judge for the Northern District of Florida, sitting by designation.

Appendix A

ANDERSON, Circuit Judge:

This case comes to us on interlocutory appeal from the district court's order granting plaintiffs' motion for partial summary judgment. The issue with which we are presented is whether the district court properly determined that two agreements among the defendants were *per se* violations of § 1 of the Sherman Act, 15 U.S.C. § 1. Because we conclude that the district court incorrectly applied the law, the order below will be reversed and the case remanded for further proceedings consistent with this opinion.

I. BACKGROUND

This is a private antitrust lawsuit, or rather numerous private antitrust lawsuits, brought against three pharmaceuticals manufacturers. The various cases asserting antitrust injury from the actions of the defendants have been consolidated by the Judicial Panel on Multidistrict Litigation in the Southern District of Florida. Plaintiffs basically assert that two agreements, one between defendant-appellant Abbott Laboratories ("Abbott") and defendant-appellant Geneva Pharmaceuticals ("Geneva") and another between Abbott and defendant Zenith Goldline Pharmaceuticals ("Zenith"),[1] entered into in 1998, violated the Sherman Act's prohibition against contracts in restraint of trade. Abbott, a manufacturer of the pioneer drug Hytrin, entered separate agreements with generic manufacturers Zenith and Geneva while those companies were pursuing FDA approval of generic versions

1. Zenith came to a tentative settlement following the district court's order granting partial summary judgment and is not a party to this appeal.

of Hytrin and while embroiled in patent litigation with those companies. Because the facts of this case took place against a complex regulatory background, we will first describe the relevant regulatory context, then the facts of the case as they appear in the current procedural posture, and then the relevant procedural history.

A. *Regulatory Framework*

No new drug can be marketed or sold in the United States without approval from the Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). Applications for FDA approval can be filed in one of two ways: as a new drug application ("NDA") under § 355(b), or as an abbreviated new drug application ("ANDA") under § 355(j). A new drug application must include exhaustive information about the drug, including reports of safety and efficacy studies. *See* 21 U.S.C. § 355(b)(1).

Prior to 1984, the NDA was the only method of obtaining FDA approval of a new drug. Every applicant had to submit safety and efficacy studies, even if such studies had already been performed for identical drugs or drugs with identical active ingredients. Adding to this inefficiency was the fact that the conduct of safety and efficacy studies would, if the new drug was the subject of a patent, constitute infringement of that patent under 35 U.S.C. § 271(a).[2] In an effort to

2. "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

eliminate these twin impediments to the introduction of generic drugs to the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. The primary accomplishments of the Hatch-Waxman Act were the creation of the ANDA, allowing a new drug applicant to piggyback on the safety and efficacy studies conducted for the pioneer drug, *see generally* 21 U.S.C. § 355(j); modification of the definition of infringement, so that the conduct of safety and efficacy studies for FDA approval is no longer infringing activity, *see generally* 35 U.S.C. § 271(e); and allowing the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was undergoing the FDA approval process, see generally 35 U.S.C. § 156.

Several of Hatch-Waxman's additions to 21 U.S.C. § 355 govern FDA approval of ANDAs in the face of patent claims by pioneer drug makers. NDA applicants are required to submit the patent number and expiration date of any patent that a generic manufacturer might infringe.[3] If such a patent issues after approval of the NDA, the holder of the application is required to file the patent number and expiration date with the FDA no later than 30 days after the patent issues. *See* 21 U.S.C. § 355(c)(2). The FDA publishes this patent information, along with other information about the drug, in what is popularly known as the Orange Book. *See* 21 U.S.C. § 355(j)(7)(A).

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3. Specifically, any patent claiming the drug or method of using the drug that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

Appendix A

An ANDA applicant relying on the safety and efficacy studies filed with the application of a drug listed in the Orange Book must make a certification with respect to each patent claiming the listed drug or a method of using the listed drug of which the applicant is aware. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The applicant must certify either that (1) the patent information has not been filed with the FDA; (2) the patent is expired; (3) the patent will expire, identifying the expiration date; or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug. If the applicant certifies (1) or (2), FDA approval proceeds in regular fashion, *see* 21 U.S.C. § 355(j)(5)(B)(i); if the applicant certifies (3), the application will not be approved until the date the relevant patent expires, *see* 21 U.S.C. § 355(j)(5)(B)(ii).

If the ANDA applicant certifies that the relevant patents are invalid or will not be infringed, commonly called a "paragraph IV certification," several things happen. First, the applicant must notify the patent holder. 21 U.S.C. § 355(j)(2)(B). If the patent holder brings suit for patent infringement[4] within forty-five days of receiving this notice,

4. It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A). This definition of infringement was added by Hatch-Waxman to allow the invocation of the procedures described in the following paragraph of this opinion.

the FDA automatically delays approval of the ANDA for thirty months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).[5] If the court hearing the infringement action declares the patent invalid or not infringed, this automatic delay in FDA approval terminates, 21 U.S.C. § 355(j)(5)(B)(iii)(I), or, if the court finds the patent valid and infringed, the approval date will be set for a date on or after the patent's expiration, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). If the court grants the patent holder a preliminary injunction prior to the expiration of the 30-month stay, the application will be approved on the date on which the court later holds the patent invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(III).

The timing of FDA approval is affected by another provision of Hatch-Waxman in the event that a listed drug is subject to more than one paragraph IV certification. Approval of an ANDA that contains a paragraph IV certification is automatically delayed if another ANDA was previously filed based on the same listed drug and the previous ANDA contains a paragraph IV certification. Approval of the subsequent ANDA is delayed until 180 days after the earlier of (1) the first commercial marketing of the drug under the previous application or (2) the date a court hearing an infringement action brought against the previous filer holds the patent invalid or not infringed.[6] *See* 21 U.S.C.

5. The patent holder is, of course, free to sue the applicant for infringement under 35 U.S.C. § 271(e)(2)(A) after the 45-day window expires. The 30-month stay of FDA approval, however, will not be triggered.

6. When the agreements at issue were entered into, the FDA regulations defined the relevant court decision triggering the end of (Cont'd)

§ 355(j)(5)(B)(iv). This delaying mechanism gives the first generic manufacturer to file a paragraph IV certification and successfully challenge the scope or validity of a patent on a pioneer drug a 180-day period during which it is the exclusive

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(Cont'd)

the 30-month stay or the start of the first filer's 180-day exclusivity period as the decision of the appellate court hearing the infringement action against the first filer. This rule was challenged in court and held invalid by *TorPharm Inc., v. Shalala*, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sept. 15, 1997), *appeal withdrawn and remanded*, 1998 U.S.App. LEXIS 4681 (D.C. Cir. Feb. 5, 1998), *vacated on other grounds* (D.D.C. April 9, 1998) (30-month stay expires upon judgment of the district court holding the patent not infringed), and by *Mylan Pharms., Inc., v. Shalala*, 81 F. Supp.2d 30 (D.D.C. 2000) (180-day exclusivity period triggered by judgment of the district court holding the patent invalid). Though the FDA was initially committed to continued adherence to the appellate judgment rule, *see* 62 Fed. Reg. 63,268 (Nov. 28, 1997), it dropped the rule following the *Mylan* decision, *see* 65 Fed. Reg. 43,233, 43,234 (July 13, 2000) (interim rule). The FDA now considers the 180-day exclusivity period to be triggered by any district court judgment holding the patent invalid, not infringed, or unenforceable, whether or not the judgment comes from the district court hearing the infringement suit against the first filer. *See Granutec, Inc. v. Shalala*, Nos. 97-1873 & 97-1874, 1998 WL 153410, *8-9 (4th Cir. April 3, 1998) (unpublished, table decision reported at 139 F.3d 889) (endorsing the FDA's position that, if the successful defense requirement is invalid, the court decision triggering the 180-day exclusivity period is the decision of any district court). *See also Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir.1999) (reversing district court's denial of an injunction to require the FDA to recognize the dismissal with prejudice of an infringement suit against a subsequent filer as triggering the first filer's 180-day exclusivity period). *See infra* at n. 12 for a discussion of the successful defense requirement.

competitor of the pioneer manufacturer. This exclusivity period is a significant incentive for generic manufacturers to challenge weak or narrow drug patents.

B. *Factual History*[7]

1. Zenith's and Geneva's ANDAs

Abbott manufactures Hytrin, a brand-name drug with the active ingredient dihydrate terazosin hydrochloride.[8] Hytrin is used to treat hypertension and enlarged prostate, and has been a very successful product for Abbott. Abbott obtained FDA approval of its NDA for Hytrin in 1987 and has held a number of patents related to terazosin hydrochloride over the years. Its first patent, issued in 1977, covered the basic terazosin hydrochloride compound. *See Abbott Labs. v. Novopharm Ltd.*, Nos. 96-C-611 & 95-C-6657, 1996 WL 131498, *1 (N.D.Ill. March 15, 1996). That patent has since expired, though Abbott has been issued other patents for various crystalline forms of the compound and various methods of using and preparing the compound.

Geneva filed four ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications with respect to Abbott's listed patents. Abbott brought

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7. The facts are largely uncontested by the parties.

8. Terazosin hydrochloride is a crystal. Dihydrate terazosin hydrochloride is a particular crystalline polymorph of terazosin hydrochloride. The opinion will refer to terazosin hydrochloride and its polymorphs simply as terazosin hydrochloride unless greater specificity is appropriate.

infringement suits under 35 U.S.C. § 271(e), invoking the 30-month stay of FDA approval of Geneva's ANDAs. On April 29, 1996, Geneva filed two additional ANDAs based on Hytrin, one for a capsule form of terazosin hydrochloride and one for a tablet form,[9] making paragraph IV certifications with respect to the relevant patents. Within forty-five days of receiving notice of Geneva's paragraph IV certifications, Abbott filed an infringement suit based on the submission of the tablet ANDA, asserting that the Geneva's tablet terazosin hydrochloride product infringed Abbott's Patent No. 5,504,207 ("the '207 patent").[10] In the suit, Geneva admitted infringement but contested the patent's validity. Apparently through oversight, Abbott failed to file an infringement suit based on the submission of the capsule ANDA. FDA consideration of that ANDA, therefore, proceeded unhindered, and Geneva's capsule ANDA was approved in March of 1998. When Abbott was notified of this approval, it began efforts to amend its complaint to allege that Geneva's terazosin hydrochloride capsule infringed the '207 patent.

Zenith, meanwhile, filed an ANDA for a terazosin hydrochloride drug[11] in June of 1994, making a paragraph

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9. The active ingredient in these two drugs is anhydrous terazosin hydrochloride.

10. The '207 patent, issued on April 2, 1996, claims a method of preparing anhydrous terazosin hydrochloride. The patent is due to expire in October of 2014.

11. The active ingredient of this drug is anhydrous terazosin hydrochloride.

IV certification with respect to Abbott's Hytrin patents. Abbott was issued a patent claiming forms of terazosin hydrochloride on May 2, 1995, Patent No. 5,412,095 ("the '095 patent"), and another on April 2, 1996, the '207 patent. Abbott timely filed this patent information with the FDA, which then required Zenith to amend its ANDA to make a certification with regard to these newly listed patents. Zenith resisted, hoping to avoid the 30-month stay of approval and the 180-day delay of approval based on Geneva's earlier-filed ANDAs.[12] Instead of certifying, Zenith brought suit against Abbott in an attempt to force Abbott to delist its '095 and '207 patents, relieving Zenith of the obligation to certify with respect to those patents, and seeking a declaration that

12. Prior to 1998, the FDA applied the "successful defense" requirement to ANDA filers hoping to take advantage of the 180-day exclusivity period. A subsequently-filed ANDA would only have its approval date delayed by 180 days if the first-filer had successfully defended against an infringement suit. *See* 59 Fed. Reg. 50,338, 50,367 (Oct. 3, 1994) (adopting successful defense regulation as a final rule, codified at 21 C.F.R. §.314.107). If Zenith's ANDA were ready for approval before Geneva successfully defended Abbott's infringement suit, then the ANDA would be approved without the 180-day delay. If Zenith were forced to make a paragraph IV certification with respect to Abbott's '095 and '207 patents, however, Abbott could invoke the 30-month stay of approval, giving Geneva more time to defend Abbott's infringement action against it.

The successful defense requirement was eventually held to be an unreasonable interpretation of the Hatch-Waxman Act by two courts of appeals. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069-70 (D.C.Cir.1998); *Granutec*, 1998 WL 153410, at *6-7. The *Mova* court enjoined the FDA from enforcing the regulation, and the FDA dropped the requirement effective November 10, 1998. *See* 63 Fed. Reg. 59,710, 59,711 (Nov. 5, 1998) (interim rule).

its terazosin hydrochloride drug did not infringe those patents. Zenith's suit alleged that Abbott listed the '095 and '207 *patents* knowing that the patents did not claim Hytrin or a method of using Hytrin. Abbott counterclaimed for infringement. Zenith's attempt to obtain a preliminary injunction against the listing of the patents was unsuccessful. *See Zenith Labs. v. Abbott Labs.*, No. 96-1661, 1997 U.S. Dist. LEXIS 23954 (D.N.J. Oct. 1, 1997). Zenith appealed the denial to the Federal Circuit.

2. The Agreements

The agreements challenged by the plaintiffs arose against this backdrop. On March 31, 1998, Abbott and Zenith entered an agreement dismissing Zenith's delisting claims and Abbott's infringement counterclaims ("Zenith Agreement"). In the Zenith Agreement, Zenith acknowledged the validity of each of Abbott's patents claiming terazosin hydrochloride and admitted that any terazosin hydrochloride product Zenith might market would infringe these patents. Zenith agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until someone else introduced a generic terazosin hydrochloride product first or until Abbott's Patent No. 4,215,532 ("the '532 patent") expired.[13] Zenith agreed not to sell or transfer its rights under any ANDA application relating to a terazosin hydrochloride drug, not to aid any other person in gaining FDA approval of a terazosin hydrochloride drug, and not to aid any other person in opposing or invalidating any of Abbott's patents

13. The '532 patent claims dihydrate terazosin hydrochloride, the active ingredient in Hytrin. That patent expired on February 17, 2000.

claiming terazosin. In return, Abbott agreed to a payment schedule according to which Abbott would pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter until March 1, 2000, or until the Agreement terminated by its own terms. If another generic manufacturer introduced a terazosin hydrochloride drug and obtained a 180-day exclusivity period, Abbott's payments would be halved until the period expired. Abbott agreed not to sue Zenith for infringement if it entered the market consistent with the Agreement.

Abbott entered an agreement with Geneva on April 1, 1998 ("Geneva Agreement"). According to the Geneva Agreement, Geneva agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until either Abbott's '532 patent expired, someone else introduced a generic terazosin hydrochloride drug, or Geneva obtained a court judgment that its terazosin tablets and capsules did not infringe the '207 patent or that the patent was invalid. This latter condition required a final judgment from which no further appeal could be taken, including petition for certiorari to the Supreme Court. Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Geneva also agreed to oppose any subsequent ANDA applicant's attempt to seek approval of its application based on Geneva's failure to satisfy the then-existing successful defense requirement and to join and support any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva's tablet ANDA. In return, Abbott agreed to pay Geneva $4.5 million each month until either someone else brought a generic terazosin hydrochloride product to market

or Abbott won a favorable decision in the district court on its infringement claim. If Geneva won in district court, Abbott's $4.5 million monthly payments would go into escrow pending resolution of the appeal, with the escrowed funds going to the party prevailing on appeal. Abbott reserved the right to terminate its payments after February 8, 2000, if no other generic terazosin hydrochloride product had been marketed as of that date. If Abbott exercised this right, it would execute a release in Geneva's favor of any claims of infringement based on the '207 patent.

3. Termination of the Agreements

The district court hearing Abbott's infringement suit against Geneva handed down its decision on September 1, 1998. *Abbott Labs. v. Geneva Pharms., Inc.*, Nos. 96-C-3331, 96-C-5868, & 97-C-7587, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998). The court held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent, *see* 35 U.S.C. § 102(b). 1998 WL 566884 at *7. Abbott appealed to the Federal Circuit, which affirmed on July 1, 1999. 182 F.3d 1315 (Fed. Cir. 1999). Abbott's petition for certiorari was denied on January 10, 2000. 528 U.S. 1078, 120 S.Ct. 796 (2000).

The Agreements did not terminate on their own terms, however. The parties terminated the Agreements on August 13, 1999, apparently in response to an FTC investigation of those Agreements. The FTC action resulted in a consent settlement. *See Matter of Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000), *also available at* http://www.ftc.gov/os/2000/05/c3945.do.htm.

Appendix A

C. *Procedural History*

All class action and individual antitrust plaintiffs filed a joint motion for summary judgment that the Agreements were *per se* illegal under § 1 of the Sherman Act on February 18, 2000. The district court issued an order granting the motion on December 13, 2000. Permission to take an interlocutory appeal from the order under 28 U.S.C. § 1292(b) was granted on April 19, 2002.

D. *The Order Granting Summary Judgment*

The December 13, 2000, Order granting plaintiffs' motion for partial summary judgment concluded that the Agreements were *per se* violations of § 1 of the Sherman Act. The Order characterized the Agreements as geographic market allocation Agreements between horizontal competitors, essentially allocating the entire United States market for terazosin drugs to Abbott, who shared its monopoly profits with the other cartel members during the life of the Agreements.

The court found that on the eve of the Agreements,

> both Geneva and Zenith were poised to market generic versions of Hytrin in the United States. Geneva received final FDA approval for its generic capsule in March subject to "validation," and the 30-month stay on its generic tablet proposal was set to expire in October. Zenith declared that it was ready to market a generic

tablet upon receipt of a favorable decision from the Federal Circuit and final FDA approval.

In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1345- 46 (S.D. Fla.2000). Despite being poised to enter the market, however, "Geneva and Zenith forswore competing with Abbott in the United States market for terazosin hydrochloride drugs. . . ." *Id.* at 1348-49.

The court identified four elements of the Agreement with Geneva that were anticompetitive: (1) Geneva's promise not to market its terazosin capsule until the Agreement terminated; (2) Geneva's promise not to market its terazosin tablet until the Agreement terminated; (3) Geneva's promise not to sell its rights in its capsule and tablet ANDAs until the Agreement terminated; and (4) Geneva's promise to aid Abbott in opposing any attempt by other ANDA applicants to enter the market before the Agreement terminated. The court identified three anticompetitive elements of the Agreement with Zenith: (1) Zenith's agreement to dismiss its delisting suit; (2) Zenith's promise not to aid any other entity's challenge to the validity of Abbott's terazosin patents; and (3) Zenith's promise not to market a generic terazosin product until the Agreement terminated. The essence of the Agreements, the court concluded, was to "dissuade[] Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period [and] eliminat[e] the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim. . . ." *Id.* at 1349.

Despite holding the Agreements *per se* unlawful, the court nonetheless entertained, and rejected, the defendants' arguments that the Agreements were either pro-competitive or benign.[14] Defendants argued that the Agreements eliminated the "substantial legal and financial risks" that accompany market entry while patent disputes remain unresolved. This justification was rejected for three reasons. First, the Agreement with Geneva was unnecessary to avoid these risks, because Geneva's unilateral decision to forego entry would achieve the same result. Second, the Agreement with Geneva did not resolve the patent litigation; "in fact, it tended to prolong that dispute to Abbott's advantage." *Id.* at 1350. The litigation was prolonged by the provisions extending the Agreement until the patent dispute was finally resolved, including Supreme Court review, and by Geneva's promise to aid Abbott in any motion seeking to extend the 30-month stay of FDA approval of Geneva's tablet ANDA. Finally, the court rejected the argument that the provision of the Agreement permitting Geneva to enter the market if Abbott elected to suspend its payments was pro-competitive. Although the court may have been willing to "infer that this clause was a catalyst for competition if Geneva paid Abbott

14. Defendants also argued that the Agreements were immune from antitrust liability under the *Noerr-Pennington* doctrine, *see United Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585 (1965); *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S. Ct. 523 (1961); that the Agreements were not subject to *per se* treatment because of their novelty; and that the Agreements could not have anti-competitive effects because independent regulatory prohibitions prevented market entry by Geneva and Zenith until at least August of 1999. The court rejected these arguments, as well. The defendants do not raise their *Noerr-Pennington* or ineffective restraints arguments on appeal.

for it, [] the suggestion that Abbott handsomely paid Geneva to spur competition in its own lucrative domestic market for terazosin hydrochloride products is patently unreasonable." *Id.* at 1351. The court did not analyze any potentially efficiency-enhancing effects of the Agreement with Zenith, concluding that the Agreement "would indefinitely postpone Zenith's entry into the United States market and would permit competition only once Abbott lost its exclusive market." *Id.*

Defendants argued that because the Agreement with Geneva was analogous to an interim patent settlement and the Agreement with Zenith terminated the litigation between Zenith and Abbott, the court should treat the Agreements as patent litigation settlements. The court rejected this argument as well, concluding that the Agreement with Geneva did not resolve Abbott's infringement suit and that the termination of litigation between Zenith and Abbott "was part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride products." *Id.* at 1353. Even if the Agreements were patent litigation settlements, the court held, such settlements were not immune from *per se* analysis. *Id.*

E. *Issues Appealed*

On appeal, Abbott and Geneva argue that the district court erred in concluding that the Agreements were *per se* violations of § 1 of the Sherman Act and that genuine issues of material fact remain in dispute.

Appellants argue that courts lack sufficient experience with agreements of the kind at issue to draw the conclusion that "history and analysis have shown that in sufficiently

similar circumstances the rule of reason unequivocally results in a finding of liability." *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1567 (11th Cir. 1991) (quotation and citation omitted). Appellants also argue that there are pro-competitive justifications for the Agreements that warrant analysis under the rule of reason. Appellants argue that genuine issues of material fact are in dispute with regard to these potential pro- competitive effects. Finally, Appellants argue that the Agreements are patent litigation settlements that must be analyzed under the rule of reason unless it is shown that the settlements were "sham."[15]

II. STANDARD OF REVIEW

We review a district court's grant of summary judgment *de novo*, applying the same legal standards applied by the district court. *Bailey v. Allgas, Inc.*, 284 F.3d 1237, 1242 (11th Cir. 2002). Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). We view the evidence in the light most favorable to the non-movant, resolving all reasonable doubts and drawing all reasonable inferences in that party's favor. *Bailey*, 284 F.3d at 1243.

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15. Indeed, all of appellants' arguments rely primarily on the circumstance that the Agreements arose in the context of patent litigation.

Appendix A

III. DISCUSSION

Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations. . . ." 15 U.S.C. § 1. It is understood that the ban on "contract[s] in restraint of trade" means only unreasonable restraints, *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S.Ct. 275, 279 (1997), that is, restraints that impair competition, *Chicago Board of Trade v. United States*, 246 U.S. 231, 238, 38 S.Ct. 242, 244 (1918). Some types of agreements are so obviously anticompetitive, or so unlikely to be pro-competitive, that such agreements can be deemed to violate the Sherman Act without much more than an examination of the agreement itself and the relationships of the parties to the agreement. *State Oil*, 522 U.S. at 10, 118 S.Ct. at 279; *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 344, 102 S.Ct. 2466, 2473 (1982). These agreements are labeled "*per se*" violations. Regardless of terminology, the ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue. *NCAA v. Bd. Regents Okla. Univ.*, 468 U.S. 85, 103, 104 S.Ct. 2948, 2962 (1984). The analytic focus should be on what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties. *See California Dental Ass'n v. FTC*, 526 U.S. 756, 779-81, 119 S.Ct. 1604, 1617- 18 (1999), *NCAA*, 468 U.S. at 103-04, 104 S.Ct. at 2961-62.

The district court focused on the agreements by Geneva and Zenith not to enter the market with FDA-approved

(or approval pending) generic terazosin drugs, holding that this exclusionary effect of the Agreements constituted an allocation of the market between horizontal competitors and that the Agreements were therefore *per se* illegal. We begin our discussion by addressing this exclusionary effect of the Agreements.

A.

An agreement between competitors to allocate markets is, as the district court noted, clearly anticompetitive. Such an agreement has the obvious tendency to diminish output and raise prices. When a firm pays its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist, competition is reduced. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50, 111 S.Ct. 401, 403 (1990) (per curiam) (agreements not to compete within certain territorial limits are obviously anticompetitive); *United States v. Topco Assocs.*, 405 U.S. 596, 608, 92 S.Ct. 1126, 1133-34 (1972) (observing that an agreement between competitors to allocate territories is a "classic example" of a *per se* violation of the Sherman Act, with no purpose other than reducing competition).

If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent. For reasons explained below, and in light of the fact that all parties seem to agree that the ANDAs that were the subjects of the

infringement suits infringed Abbott's '207 patent, we reject the district court's characterization of the instant Agreements as illegal *per se*. We believe any such characterization is premature without further analysis of the kind suggested in this opinion. Because the market allocation characterization was central to the district court's conclusion that the Agreements in their entireties are *per se* violations of § 1 of the Sherman Act, we will reverse the grant of summary judgment.

A patent grants its owner the lawful right to exclude others. *See* 35 U.S.C. §§ 271(a) (defining infringement) & 283 (providing injunctive relief for infringement); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S.Ct. 2601, 2623 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions. *Bonito Boats, Inc., v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51, 109 S.Ct. 971, 977-78 (1989); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C. Cir. 1981). The exclusionary right cannot be exploited in every way—patentees cannot pool their patents and fix the prices at which licensees will sell the patented article, for example, *see United States v. New Wrinkle, Inc.*, 342 U.S. 371, 72 S.Ct. 350 (1952)—but a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself, *see, e.g., In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1209 (2d

Cir. 1981); or grant exclusive territorial licenses carving up the United States among its licensees, *see* 35 U.S.C. § 261. Within reason, patentees can also subdivide markets in ways other than territorial, such as by customer class. *Gen. Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 58 S.Ct. 849, *aff'd on reh'g*, 305 U.S. 124, 59 S.Ct. 116 (1938) (approving a license restricting the licensee's sales to non-commercial customers). Such arrangements undoubtedly tend to result in lower production and higher prices of the patented article than if competition were unrestrained, but these anticompetitive tendencies do not render them in violation of the Sherman Act.

The above discussion illustrates the point that a patentee's allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability, and this is so because the patent gives its owner a lawful exclusionary right. In characterizing the Agreements as territorial market allocations agreements, the district court did not consider that the '207 patent gave Abbott the right to exclude others from making, using, or selling anhydrous terazosin hydrochloride until October of 2014, when it is due to expire.[16] To the extent that Zenith and Geneva agreed not to market admittedly infringing products before the '207 patent expired or was held invalid, the market allocation characterization is inappropriate.

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16. The '207 patent was, of course, declared invalid on September 1, 1998, a judgment affirmed on January 10, 2000. The antitrust consequences of this subsequent invalidation will be addressed below.

Appendix A

Zenith's agreement not to market an infringing generic terazosin hydrochloride drug terminated, by its own terms, when either another generic manufacturer marketed a terazosin product and any exclusivity period expired or Abbott's '532 patent expired in February of 2000. The effect of the Zenith Agreement on the production of Zenith's infringing terazosin product appears to be no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent it permitted Zenith to market its drug before the '207 patent expired. Geneva's agreement not to market an infringing terazosin product terminated at the earliest of (1) a final, unappealable judgment holding the '207 patent invalid; (2) the marketing of a terazosin product by another generic manufacturer; or (3) the expiration of the '532 patent. The effect of the Geneva Agreement on the production of Geneva's infringing generic terazosin product may have been no broader than the potential exclusionary effect of the '207 patent. The '207 patent may have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal, which also would have prevented Geneva from marketing its terazosin hydrochloride products during this period.[17]

With respect to the foregoing aspects of the two Agreements' exclusionary effects, which were the foundation of the district court's characterization of the Agreements as

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17. We say "may" because we do not hold that the '207 patent would have allowed Abbott to obtain a preliminary injunction or a stay of an adverse judgment pending appeal. We mean only that these are among the considerations that the district court should address on remand. We do note that appellees have not at this stage argued that Abbott would have been unable to obtain such relief.

market allocation agreements, these are at the heart of the patent right and cannot trigger the *per se* label.[18] Unlike some kinds of agreements that are *per se* illegal whether engaged in by patentees or anyone else, such as tying or price-fixing, the exclusion of infringing competition is the essence of the patent grant. As one court has concluded, "when patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is *per se* illegal." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003). Because the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed and its conclusion that these Agreements constitute *per se* violations of the antitrust laws must be reversed.

While our holding at this early stage of the litigation is appropriately narrow, the decision below and the arguments

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18. Appellees argue that the Agreements have broader exclusionary tendencies in that they also prohibited the marketing of non-infringing terazosin products, prohibited Geneva from marketing infringing products beyond the date a district court held the '207 patent invalid, and prohibited Geneva from waiving its 180-day exclusivity period. As we explain below, these prohibitions may be beyond the scope of Abbott's lawful right to exclude and, if so, would expose appellants to antitrust liability for any actual exclusionary effects resulting from these provisions that appellees can prove at the causation and damages stages of litigation. Our point thus far is that appellees have failed to prove that appellants should face *per se* antitrust liability for treble damages for the failure of Zenith and Geneva to market admittedly infringing products when no court had declared Abbott's patent invalid or unenforceable at the time of the Agreements.

of the parties invite our discussion of several matters that promise to be relevant on remand. We first discuss appellees' argument that the antitrust analysis need not consider Abbott's patent rights because the '207 patent was declared invalid. We then discuss appellees' argument that the lawful right of exclusion does not include the right to pay competitors not to produce infringing products. Finally, we offer several observations with respect to the framework to be developed on remand for deciding the appropriate antitrust analysis.

B.

The individual Sherman Act plaintiffs-appellees argue that because the '207 patent was declared invalid after the Agreements were entered into, Abbott never had any patent rights and our antitrust analysis need not consider the '207 patent. We reject the appellees' argument that the agreements by Geneva and Zenith not to produce infringing products are subject to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid. We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into. *Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985); *SCM Corp.*, 645 F.2d at 1207. At the time the Agreements were entered into, no court had declared Abbott's '207 patent invalid, and the appellees have advanced no argument other than mere invalidity.[19] We hold that the mere subsequent invalidity of

19. That is, appellees have neither alleged nor asserted that the patent was procured by fraud, that appellants knew the patent was invalid, that there was no objective basis to believe that the patent

the patent does not render the patent irrelevant to the appropriate antitrust analysis.

The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim, *see Walker Process Equip., Inc., v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179, 86 S.Ct. 347, 351 (1965) (Harlan, J., concurring), or as a limited exception to the general rule that markets should be free from barriers to competition, *see id.*, 382 U.S. at 176, 86 S.Ct. at 350; *United States v. Line Material Co.*, 333 U.S. 287, 309, 68 S.Ct. 550, 561 (1948); *id.*, 333 U.S. at 310, 68 S.Ct. at 562. Appellees' argument implies that this defense is unavailable with respect to the Agreements because the '207 patent was subsequently held invalid.

The only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced, it held that the antitrust claimant must prove that the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office. *Walker Process*, 382 U.S. at 177, 86 S.Ct. at 350 (considering a monopolization claim against a patentee for suing to enforce a patent allegedly procured by fraud). Good faith procurement furnishes a complete defense to the antitrust claim. *Id.* Justice Harlan's concurrence explained that the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must

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was valid, or any such similar allegations. We therefore are not called upon to decide what the antitrust consequences of such circumstances might be.

be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws:

> It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under § 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed to reach § 2 monopolies carried on under a nonfraudulently procured patent.

382 U.S. at 179-80, 86 S.Ct. at 351-52. This approach is commonly used by courts considering the intersection of patent law and antitrust law. *See, e.g., SCM Corp.*, 645 F.2d

at 1203-06 (considering antitrust claims against a patentee for acquiring and refusing to license various patents); *Handgards, Inc., v. Ethicon, Inc.*, 601 F.2d 986, 992-93 (9th Cir. 1979) (considering a monopolization claim against a patentee for asserting a patent it allegedly knew to be invalid). A suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system is required by the complementary objectives of the two:

> It is commonly said . . . that the patent and antitrust laws necessarily clash . . . At the same time, the two regimes seek the same object: the welfare of the public . . . [A]ntitrust law forbids certain agreements tending to restrict output and elevate prices and profits above the competitive level. Patent law also serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.

H. Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 1780a (1999) ("Hovenkamp") (citations and quotations omitted). *See also* D. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 Fla. L. Rev. 747, 748 n.1 (2002) ("It is generally recognized that antitrust and patent law, although polar opposites in their treatment of monopolies, share common objectives."); *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1352 (Fed. Cir. 1999) ("The patent and antitrust laws are complementary in purpose in that they each promote innovation and competition. . . .") (citation omitted).

Employing this approach, we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives. Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.[20] This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation. *See Ciprofloxacin*, 261 F. Supp. 2d at 256 (expressing concern for the effect of settlement-restricting antitrust liability rules on the incentives for research and development); *cf. Walker*

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20. The cost and complexity of most patent litigation is a familiar problem to the court system. *See, e.g., Blonder-Tongue*, 402 U.S. at 331-32 & 334-38, 91 S.Ct. at 1444 & 1445-48 (1971); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1475-76 (Fed. Cir. 1998) (Rader, J., dissenting) (discussing claim construction); *Matter of Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, *166-67 & *239-40 (F.T.C. June 27, 2002), *also available at* http://www.ftc.gov/os/caselist/d9297.htm. *See also* Crane, 54 Fla. L. Rev. at 757. The cost savings of settlement, both to the parties and to the public, are equally widely-recognized. *See Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) ("Public policy favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming.").

Process, 382 U.S. at 180, 86 S.Ct. at 352 (Harlan, J., concurring) (permitting antitrust liability based on a showing that mere invalidity "might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damages suits").

There may be circumstances under which the unreasonableness of a settlement agreement regarding a subsequently-invalidated or unenforceable patent would be sufficiently apparent that antitrust liability would not undermine the encouragement of genuine invention and disclosure. *Cf. Walker Process*, 382 U.S. at 179-80, 86 S.Ct. at 351 (Harlan, J., concurring) (noting that exposing patentees to antitrust liability for the assertion of a patent known to have been procured by fraud "cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure"). In this regard we note that some lower courts have extended *Walker Process* to permit antitrust claims against patentees for the anticompetitive effects of infringement lawsuits when the antitrust claimant proves that the patentee knew that the patent was invalid, *Handgards*, 601 F.2d at 994-96, or knew that the patent was not infringed, *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876-77 (Fed. Cir. 1985), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).[21] To the extent that the appellees have

21. Similarly, it has been suggested that the "sham" exception to the antitrust immunity afforded by the *Noerr-Pennington* doctrine is or may be available also to antitrust plaintiffs seeking to pierce the patent immunity. *See In re Indep. Serv. Orgs. Antitrust Litig.*, 203

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demonstrated nothing more than subsequent invalidity, we hold that this alone is insufficient to render the patent's potential exclusionary effects irrelevant to the antitrust analysis.

C.

The class action plaintiffs-appellees argue that the patent right does not include the right to pay infringers, with the implication that any exclusion resulting from payment rather than judicial enforcement is not protected from *per se* antitrust liability by the patent laws. Our discussion with regard to the important role played by settlement in the enforcement of patent rights leads us to reject this argument as well. Appellees have not explained why a monetary payment as part of a patent litigation settlement should be flatly prohibited as a *per se* violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with. *See Ciprofloxacin*, 261 F. Supp.2d at 251-52 (discussing the asymmetries of litigation risk created by Hatch-Waxman and rejecting the argument that payments from the patentee to the infringer are subject to *per se* antitrust analysis); Crane, 54 Fla. L. Rev. at 774 (discussing the dynamics of settlement before the alleged infringer has entered the market).

We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater

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F.3d at 1326-27. Because the parties have not briefed such potential exceptions to the patent immunity from antitrust liability, we do not address them at this time.

than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. *See Aro Corp.*, 531 F.2d at 1372. To hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a *per se* rule would be an appropriate accommodation of the competing policies of the patent and antitrust laws.

It may be that the size of the payment to refrain from competing, sometimes called a "reverse payment" or an "exit payment," raises the suspicion that the parties lacked faith in the validity of the patent,[22] particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim (as a bond posted as part of a preliminary injunction would be). However, in the instant case and given the state of the current record, it is difficult

22. For example, the size of the payments might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid. *See* discussion in Part B, *supra*.

to infer from the size of the payments alone that the infringement suits lacked merit. We do not know, for example, what lost profits Abbott expected from generic competition or what profits Geneva and Zenith expected to gain from entry, the risk of the defendants' inability to satisfy a judgment, or the litigation costs each side expected to save from settlement. We do not know how much of the payment might have been in exchange for provisions of the Agreements other than Zenith's and Geneva's acknowledgment of validity.[23] Without these facts we cannot confidently draw the conclusion, merely from the size of the payments, that there were no genuine disputes over the validity of the patent. Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement. *See, e.g.*, *Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 196, 234 (settlement agreements under which a patentee paid an infringer $49.1 million to acknowledge the validity of a patent, and at least $398 million for the infringer to remain off the market, though the patent was subsequently approved by the PTO on reexamination and unsuccessfully challenged in court three times).

Another possibly suspicious characteristic of the payments to Geneva is their structure (*i.e.*, tying their duration to the length of the litigation), which, as the district court noted, may have given Geneva an incentive to delay

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23. For example, it seems reasonable to assume that part of the payments to Geneva were in return for Geneva's agreement not to waive its 180-day exclusivity period. Payments for provisions other than the acknowledgment of validity would not shed light on the parties' evaluations of the merits of the validity issue.

resolution of the infringement suit.[24] But if the payments were in furtherance of the seemingly reasonable purpose of compensating Geneva for any lost profits during the course of litigation (much like a bond posted as part of a preliminary injunction), it is difficult to imagine how else to structure the payments but by tying them to the length of the litigation.

We recognize that the Sixth Circuit appeared to take the opposite view in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) ("[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competition by paying the only potential competitor $40 million per year to stay out of the market.").[25] When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion. "[T]he protection of the patent laws and the coverage of the antitrust laws are not separate issues." *Studiengesellschaft*, 670 F.2d at 1128. As the above discussion indicates, we do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws,[26] nor do we think that

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24. Neither appellees nor the district court have offered any similar suspicions with regard to the structure of payments under the Zenith Agreement.

25. The terms of the agreements at issue in the *Cardizem CD* case were similar to the terms of the Agreements in this case.

26. The Sixth Circuit seems to have placed considerable reliance upon the generic's agreement to delay entering the market in exchange

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the evidence regarding the exit payments in this case allows a confident conclusion to be drawn at this stage of the litigation that the exclusionary effect of the Agreements were bolstered by the exit payments to a degree that exceeds the potential exclusionary power of the patent.

Because these matters were given scant attention in the district court, considering the court's primary conclusion that the Agreements were market division agreements like those in *Palmer* and *Topco*, these questions have not been explored. We simply note them here to explain our conclusion that the presence of an exit payment as part of the settlement does not alone demonstrate that the Agreements had obvious

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for exit payments, although it may also have been influenced by other provisions of the agreement which might more readily seem to exceed the potential exclusionary power of the patent. For example, the Sixth Circuit mentioned the effect of the agreements regarding the 180-day exclusivity period as well, and its reference to the district court opinion in that case might reflect some reliance on the restriction on non-infringing products. *See Cardizem CD*, 332 F.3d at 907-08; *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 705 (E.D. Mich. 2000). However, the Sixth Circuit opinion did not purport to measure the several provisions against the exclusionary power of the patent, or differentiate between provisions that fell within the scope of the patent's protection and those which did not. *Cf. Cardizem CD*, 105 F. Supp. 2d at 701 ("The anticompetitive effects of [the] patent are likewise not at issue."). To the extent that the Sixth Circuit suggests that a settlement of patent litigation was a *per se* violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, we respectfully disagree. We believe that the potential exclusionary power of the patent must first be considered.

anticompetitive tendencies above and beyond Abbott's potential exclusionary rights under the '207 patent.

D.

Our discussion so far has been limited to the exclusionary effects of the instant Agreements to delay entrance into the market, the subsequent invalidation of the patent, and the mere fact of exit payments. To the extent that these or other effects of the Agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to *per se* antitrust condemnation.[27] From the preceding discussion, we conclude that deciding the antitrust implications of these exclusionary effects requires an analysis of the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of "achieving a suitable accommodation between the differing policies." *Walker Process*, 382 U.S. at 179, 86 S.Ct. at 351 (Harlan, J., concurring).

As alluded to earlier, however, *see supra* at __ n.18 (M/S at 26, n.18), the instant Agreements are not confined to matters involving restrictions on infringing products, exit payments, and a subsequent court decision declaring the

27. Application of rule of reason analysis is similarly inappropriate, as the anticompetitive effects of exclusion cannot be seriously debated. Rule of reason and *per se* analysis are both aimed at assessing the anticompetitive effects of particular conduct; what is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.

patent invalid. Appellees also challenge other provisions of the Agreements, such as those prohibiting the marketing of "any" generic terazosin product; Geneva's agreement not to waive its 180-day exclusivity period; and Geneva's agreement not to come to market until a final, unappealable judgment of invalidity rather than on a district court judgment. These arguments require consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the Agreements exceed that scope, and the anticompetitive effects thereof. Because these considerations require a different analytic framework than that applied by the district court and advocated by the parties on appeal, it is appropriate to remand to the district court to apply an appropriate framework derived from this decision, and the arguments of the parties and the facts developed on remand. To aid in the development of an appropriate framework, we offer the following observations.

We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted the patentee. "[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise." *Line Material*, 333 U.S. at 300, 68 S.Ct. at 557. *See also New Wrinkle*, 342 U.S. at 378, 72 S.Ct. at 353 ("Patents give no protection from the prohibitions of the Sherman Act to [price fixing] when the licenses are used, as here, in the scheme to restrain."); *United States v. Masonite Corp.*, 316 U.S. 265, 277, 62 S.Ct. 1070, 1077 (1942) ("The owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant.").

The appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law[28] and consideration of the extent to which the Agreements reflect a reasonable implementation of these. Appellants, for example, contend that certain provisions of the Geneva Agreement are analogous to a consensual preliminary injunction and stay of judgment pending appeal. To evaluate this claim, the provisions of this Agreement should be compared to the protections afforded by the preliminary injunction and stay mechanisms and considered in light of the likelihood of Abbott's obtaining such protections. *Cf.* Hovenkamp at ¶ 2046 ("some care must be taken to ensure that . . . the settlement . . . is not more anticompetitive than a likely outcome of the litigation").

Any provisions of the Agreements found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act.[29] *Standard Oil Co., Ind., v. United States*, 283 U.S. 163, 175,

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28. We express no view at this time on what role the FDA's regulation of market entry might play in the appropriate antitrust analysis.

29. Courts have not hesitated to apply traditional antitrust principles to agreements not within the scope of the patent protection. *See Line Material*, 333 U.S. at 307, 68 S.Ct. at 560 (holding a patent pooling agreement that fixed the prices at which licensees would sell the patented product *per se* illegal); *Masonite*, 316 U.S. at 274, 62 S.Ct. at 1076 (holding a price-fixing agreement among patentees and their licensees *per se* illegal).

51 S.Ct. 421, 425-26 (1931) (recognizing that cross-licensing agreements and a division of royalties could be used to monopolize or fix prices and examining the evidence to assess the potential for anticompetitive effects as a result of the agreements at issue). The appropriate analysis of the market effects of such provisions may depend on the nature of the provision challenged. It may be that some challenged provisions are so obviously anticompetitive that they can be condemned as illegal on the evidence so far adduced, or it may be that the tendencies of some challenged provisions cannot be confidently predicted without further inquiry.

> [T]here is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.

Cal. Dental, 526 U.S. at 780-81, 119 S.Ct. at 1618.[30] If on remand the court should conclude that part, but not all, of

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30. Because the appellants' arguments supporting the application of the rule of reason rely primarily on the circumstance that the Agreements arise out of patent litigation, and because the determination of the appropriate analysis should await the inquiries to be made on remand, we decline at this time to address the issue further. We note, however, that the application of the rule of reason is not synonymous with exhaustive factual inquiry. "[S]ome rule-of-reason cases can be disposed of merely on the basis of the parties' arguments and, more often, on the basis of a limited summary judgment record." Hovenkamp, ¶ 1508.

the provisions of the Agreements violate the Sherman Act, it may also be helpful to identify with specificity which provisions or combination of provisions are illegal[31] and the nature of the anticompetitive effects of those provisions or combinations in order to aid subsequent determinations on causation and antitrust injury. Finally, the particular circumstances of this case and the arguments of the parties on remand may demonstrate other relevant considerations.

IV. CONCLUSION

The district court's order granting partial summary judgment is REVERSED and this case is REMANDED for further proceedings consistent with this opinion.[32]

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31. This is not to suggest that the provisions should be considered in isolation; agreements that are anticompetitive when considered in isolation (such as covenants not to compete) can still be lawful if they are ancillary to another agreement and, when viewed in combination, will have the overall effect of enhancing competition. *See Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 729, 108 S.Ct. 1515, 1523 & n.3 (1988), *Polk Bros.*, 776 F.2d at 189. We simply suggest that careful consideration of individual provisions may be helpful should it appear that the Agreements are unlawful only in part.

32. All pending motions are DENIED.

APPENDIX B — ORDER GRANTING PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND DENYING DEFENDANT ZENITH'S MOTION FOR SUMMARY JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA, SOUTHERN DIVISION FILED DECEMBER 13, 2000

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
SOUTHERN DIVISION

CASE NO. No. 99-MDL-1317-SEITZ/GARBER
ALL SHERMAN ACT CASES

In re TERAZOSIN HYDROCHLORIDE ANTITRUST LITIGATION

ORDER GRANTING PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND DENYING DEFENDANT ZENITH'S MOTION FOR SUMMARY JUDGMENT

After defendant Zenith Goldline Pharmaceuticals, Inc. ["Zenith"] moved for summary judgment on the plaintiffs' federal antitrust complaints [D.E. No. 77, Civ. No. 98-3125; D.E. No. 45, Civ. No. 99-1938], the Sherman Act Plaintiffs[1] sought a partial summary judgment [D.E. No. 21, Civ. No. 99-MDL-1317] that defendant Abbott Laboratories ["Abbott"] contracted with defendants Zenith and Geneva

1. The term "Sherman Act Plaintiffs" refers to all plaintiffs who allege violations of the Sherman Antitrust Act in the individual and class cases consolidated before the Court.

Pharmaceuticals, Inc. ["Geneva"], to secure the entire domestic market for prescription drugs containing terazosin hydrochloride in violation of section one of the Sherman Antitrust Act, 15 U.S.C. § 1. The undisputed facts in this case demonstrate that Abbott's agreements with its horizontal competitors would tend to impair domestic competition and restrain the trade of terazosin hydrochloride products. American courts have long condemned such agreements as illegal *per se* under the Sherman Act. Accordingly, the Court will grant the requested partial summary judgment to the plaintiffs, deny defendant Zenith's motion for summary judgment without prejudice, and allow the parties to conduct full discovery on the issues of causation and damages.

BACKGROUND

1. Stirrings of a Competitive Market for Terazosin Hydrochloride

Abbott developed terazosin hydrochloride for the treatment of hypertension and enlarged prostate and sought the Food and Drug Administration's ["FDA"] approval to market the drug by filing a New Drug Application ["NDA"]. Pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-91 ["FDCA"], FDA examined terazosin hydrochloride's safety and efficacy and approved it for human consumption, publishing three of Abbott's claimed patents in the publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," affectionately known as the "Orange Book."

Appendix B

In 1987, Abbott began exclusively marketing terazosin hydrochloride under the trademark "Hytrin" in tablet and capsule forms. Hytrin has been lucrative for Abbott. According to the Federal Trade Commission, Hytrin generated $540 million in sales in 1998, accounting for more than twenty percent of Abbott's net sales of pharmaceutical products in the United States.[2]

Beginning in 1990, generic drug maker Geneva took steps to compete with Abbott by developing a generic terazosin hydrochloride drug that could contain different inactive ingredients and be sold without a brand name in tablet and capsule forms. Taking advantage of the "Hatch-Waxman Amendments" to FDCA that streamlined the evaluation process for proposed generic drugs,[3] Geneva applied for FDA approval by submitting four Abbreviated New Drug Applications ["ANDAs"] between 1993 and 1996.

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2. (*See Compl., Abbott Labs.*, No. C-3945, at ¶ 10 (FTC May 22, 2000), *available at* http://www.ftc.gov/os/2000/05/abbottgenevacomp.htm *and reprinted in* Zenith Notice, Ex. B, Civ. No. 99-MDL-1317, Mar. 20, 2000); *see also* FEDERAL TRADE COMMISSION, ANALYSIS TO AID PUBLIC COMMENT (2000), *available at* http://www.ftc.gov/os/2000/05/abbottgenevaanalysis.htm ["ANALYSIS"]. The Federal Trade Commission recently concluded an investigation into the Abbott-Geneva accord by entering a consent decree prohibiting similar accords. *See* ANALYSIS ¶ 21. That decree does not govern the Court's decision.

3. Drug Price Competition & Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355). The declared purpose of this legislation was to "make available more low cost generic drugs." H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

Appendix B

Geneva's ANDAs relied on data concerning Hytrin's safety and efficacy, asserted that the proposed generic drug was "bioequivalent" to Hytrin, and certified under paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) that the proposed drug did not infringe any *valid* patent claimed by Abbott for Hytrin.

When Abbott received notice of Geneva's "paragraph IV certifications" challenging its patents, it exercised its statutory right to sue Geneva within forty-five days for patent infringement under 21 U.S.C. § 355(j)(5)(B)(iii) by instituting several actions in the United States District Court for the Northern District of Illinois. By statute, these suits effectively prevented FDA from approving Geneva's disputed ANDAs for 30 months unless Abbott's Hytrin patents were declared "invalid or not infringed." *Id.* § 355(j)(5)(B)(iii)(I).

The Hatch-Waxman Amendments to FDCA furnished a significant incentive for Geneva to raise the first challenge to Abbott's Hytrin patents, namely, exclusive marketing rights to the first generic version of Hytrin for 180 days. *Id.* § 355(j)(5)(B)(iv). Under the "successful defense" regulation that FDA promulgated to implement this statutory incentive, however, Geneva needed to obtain a final decision of non-infringement from either the trial court or the Court of Appeals for the Federal Circuit in order to perfect its entitlement to the 180-day exclusive marketing period. *See* Abbreviated New Drug Application Regs., 54 Fed.Reg. 28,872, 28,894 (July 10, 1989); Abbreviated New Drug Application Regs., Patent and Exclusivity Provisions, 59 Fed.Reg. 50,338, 50,350-55 (Oct. 3, 1994). If another generic drug maker, such as Zenith, challenged Abbott's patents and successfully defended its ANDA first, Geneva would not be entitled to this statutory incentive. Zenith would

be able to market the first generic terazosin hydrochloride drug, albeit without exclusive marketing rights to delay its competitors from entering the marketplace.

In June, 1994, Zenith joined the race to bring the first generic terazosin hydrochloride drug to market by filing an ANDA featuring a paragraph IV certification on one of Abbott's Hytrin patents. (Zenith Mem., Oct. 22, 1999, Ex. 6, at 11.) Abbott brought two unsuccessful infringement suits against Zenith for infringement of this patent, which was not timely included in the Orange Book. *See Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 939 (N.D.Ill.1995) (dismissing case and observing that Abbott retained right to sue Zenith for patent infringement "upon the commencement of marketing . . . of the generic copy"). Abbott then submitted two additional patents to FDA for inclusion in the Orange Book, U.S. Patents 5,412,095 [" '095 patent"] and 5,504,207 [" '207 patent"]. In March, 1996, FDA informed Zenith that it would have to amend its ANDA to certify with respect to those patents. Zenith balked at amending its ANDA, however, because Abbott then could institute another infringement suit and trigger a new 30-month stay of FDA approval (absent an intervening judicial determination of non-infringement) of Zenith's proposed generic tablet. On April 15, 1996, Zenith sued Abbott for improperly listing the '095 and '207 patents, and requested injunctive relief delisting them from the Orange Book. Abbott counterclaimed, alleging that Zenith had infringed those patents.

Later that month, on April 29, 1996, Geneva renewed its drive to market the first generic tablet and capsule versions of Hytrin by filing an ANDA featuring a new paragraph IV

certification with respect to Abbott's recently- listed '207 patent. Abbott launched an infringement action to stop Geneva's new generic tablet proposal, but inexplicably failed to protest Geneva's new generic capsule proposal. FDA continued to evaluate the safety and efficacy of Geneva's proposed capsule while the automatic 30-month stay for approval of Geneva's proposed tablet took effect.

2. The Survival of the "Successful Defense" Requirement

In 1997, two federal courts rendered conflicting decisions on the validity of the successful defense requirement, temporarily throwing into question which drug maker would market the first generic version of Hytrin. On January 23rd, the United States District Court for the District of Columbia strongly questioned the validity of the successful defense regulation and concluded that the first drug maker to file an ANDA for a generic micronized glyburide product, Mova Pharmaceutical Corp., was entitled to exclusive marketing rights to that product for 180 days despite the fact that one of its competitors, Mylan Pharmaceuticals, Inc., filed a micronized glyburide ANDA later and successfully defended it first. *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131-32 (D.D.C.1997); *id* at 130 (enjoining FDA from enforcing regulation against plaintiff because underlying statute "does not include a 'successful defense' requirement"). FDA briefly ceased enforcing its regulation "in order to promote administrative uniformity and to avoid [judicial] forum shopping problems," but on July 3rd, Judge Boyle of the United States District Court for the Eastern District of North Carolina upheld the validity of the

successful defense regulation and enjoined FDA from *refusing* to enforce it. *See Granutec, Inc. v. Shalala,* 1998 WL 153410, at *1 (4th Cir. Apr.3, 1998) (recounting history of unreported District Court case). The Court of Appeals for the Fourth Circuit promptly stayed this injunction pending appeal. *Id.* at *5.

On November 5, 1997, FDA announced that it would enforce the successful defense regulation and await the decision of the appellate courts before revising its standards. Policy on 180-Day Marketing Exclusivity for Drugs Marketed under Abbreviated New Drug Applications; Clarification, 62 Fed. Reg. 63,268, 63,269 (Nov. 28, 1997). Thus, despite the decision of the United States District Court for the District of Columbia in the *Mova* case, Geneva would have to successfully defend its ANDA against Abbott's infringement suit before Zenith successfully defended its ANDA in order to market the first generic version of Hytrin.

While *Mova* and *Granutec* were pending before the federal Courts of Appeal, Zenith's campaign to beat Geneva to the market also suffered a setback. On October 1, 1997, the United States District Court for the District of New Jersey rejected Zenith's complaint for injunctive relief to delist Abbott's '095 and '207 patents, at least temporarily blocking final FDA approval of Zenith's ANDA. *See Zenith Labs., Inc. v. Abbott Labs.*, Civ. No. 96- 1661, slip. op. at 26-27 (D.N.J. Oct. 1, 1997). Zenith appealed this decision to the Court of Appeals for the Federal Circuit. Then, on February 27, 1998, Zenith asked FDA to develop "a plan of action . . . to expedite final approval of Zenith's ANDA upon the delisting of Abbott's patents," so Zenith could "immediately

bring [its] product to market should [it] receive a favorable court ruling." (Walgreen Pls.' Opp'n, Nov. 8, 1999, Ex. 3 (Letter from Jason A. Gross, Director, Zenith Regulatory Affairs, to Douglas L. Sporn, Director, FDA Office of Generic Drugs (Feb. 27, 1998) (previously filed under seal)).)

In late March, 1998, both Geneva and Zenith were poised to market generic versions of Hytrin in the United States. Geneva received final FDA approval for its generic capsule in March subject to "validation,"[4] and the 30-month stay on its generic tablet proposal was set to expire in October. Zenith declared that it was ready to market a generic tablet upon receipt of a favorable decision from the Federal Circuit and final FDA approval.[5] But competition between Abbott, Geneva, and Zenith for the United States market for sales of terazosin hydrochloride drugs did not materialize.

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4. "Validation" refers to the process by which a drug maker produces three commercial-size batches of the approved drug to prove that its product meets the technical specifications contained in the relevant ANDA. *See* FOOD & DRUG ADMIN., GUIDELINE ON GENERAL PRINCIPLES OF PROCESS VALIDATION (1987), *reprinted in* Geneva Opp'n, Ex. 3-A, Mar. 21, 2000; *see also* 21 C.F.R. § 211.110; (Geneva Opp'n, Ex. 3, at 3 (Aff. of Joan Fiore, Geneva Project Manager)).

5. (*See* Walgreen Pls.' Opp'n, Ex. 4 (Declaration of Karen Rocco, Associate Director, Zenith Regulatory Affairs, at ¶ 5).) According to the defendants, by filing the first ANDA on Abbott's patents, Geneva precluded Zenith from introducing the first generic version of Hytrin. (*E.g.*, Abbott Statement, Mar. 20, 2000, at 14.) This statement draws a legal conclusion and conflicts with the state of the law at the time of the defendants' agreements. *See infra* note 12 and accompanying text.

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3. Abbott's Accords with Zenith and Geneva

Abbott and Zenith informed the Federal Circuit on March 20, 1998, that they were settling their dispute and asked the Court to hold Zenith's appeal in abeyance. Then, on March 30th, Abbott received word that FDA had approved Geneva's generic terazosin hydrochloride capsule. During the following two days, Abbott entered into separate confidential agreements with Zenith and Geneva to alter each company's rights and responsibilities.

Under its March 31, 1998, "Settlement Agreement," Zenith agreed to accept $3 million to join Abbott in dismissing the disputes before the District of New Jersey and the Federal Circuit, and to accept an additional $6 million per quarter (or a prorated sum for a shorter period) to "not sell, offer for sale, donate, or otherwise commercially distribute in the United States any [t]erazosin [h]ydrochloride [p]roduct" until another drug maker sold a generic version of Hytrin in the United States, Abbott elected to "allow[] Zenith to enter the market," or Abbott's patents expired. (*See* Pl.'s Mem., Feb. 18, 2000, Ex. 1, at 2, 3, 5 (Zenith-Abbott Agreement (Mar. 31, 1998)) ["Zenith Agreement" or "Z.A."].)[6] Zenith also promised "not [to] aid or assist any person or entity to gain FDA approval to market a[t]erazosin [h]ydrochloride [p]roduct," and obtained Abbott's permission to market such products once generic competition began. (*Id.* at 7, 4.)

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6. Zenith would receive only $3 million for the first quarter that it refrained from marketing a generic version of Hytrin, (*id.* at 3), but if Geneva ultimately enjoyed exclusive marketing rights by statute for 180 days, Abbott would pay Zenith three million dollars during that period as well. (*Id.* at 4.)

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On April 1, 1998, Geneva agreed to accept $4.5 million per month from Abbott (or a prorated sum for a shorter period) to refrain from marketing any generic terazosin hydrochloride drug, including its FDA-approved capsule, until another drug maker sold a generic version of Hytrin in the United States or Geneva received a final, unappealable judgment that its proposed generic tablet did not infringe Abbott's patents. (*See* Pl.'s Mem., Ex. 2, at 2-5 (Geneva-Abbott Agreement (Apr. 1, 1998)) ["Geneva Agreement" or "G.A."].)[7] Geneva and Abbott agreed to continue their court battle over the proposed generic terazosin hydrochloride tablet. Geneva promised to "join and support any motion filed by Abbott . . . in the Northern District of Illinois" seeking an extension of FDA's 30-month stay on approval of its proposed tablet. (*Id.* at 5.) If Geneva successfully defended Abbott's suit before the trial court, Abbott would pay subsequent monthly payments into an escrow fund payable to the final prevailing party on appeal, whether before the Federal Circuit or the Supreme Court. Geneva also pledged not to transfer the rights to its ANDAs or the FDA-approved capsule. If Abbott elected to terminate its payments in February, 2000, Geneva would enjoy the right to market terazosin hydrochloride products in the United States without objection. (*Id.* at 4.)

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7. Abbott reserved the right to suspend its payments to Geneva, promising "not to sue it for patent infringement . . . of the '207 patent," if no drug maker introduced a generic version of Hytrin by February 18, 2000. (*Id.* at 4.) For its part, Geneva promised "to use its best efforts to oppose any attempts by any ANDA applicant that is a party to litigation involving terazosin hydrochloride patents to assert that it is entitled to approval of its ANDA . . . prior to the date currently determined pursuant to 21 C.F.R. § 314.107." (*Id.* at 5.)

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On April 2, 1998, and for the following sixteen months, Abbott sold the only terazosin hydrochloride drug available in the United States.

DISCUSSION

As previously mentioned, the Sherman Act Plaintiffs seek a partial summary judgment that the defendants committed a *per se* violation of section one of the Sherman Act by contracting to allocate the United States market for terazosin hydrochloride products, thereby stifling domestic competition and restricting the output and sale of generic versions of Hytrin. The defendants counter that the challenged agreements tended to foster competition, imposed only incidental restraints on generic drug production mirroring those imposed by law, and caused no harm to the plaintiffs. Zenith, in particular, relies on these arguments and others to establish that it is entitled to summary judgment on the plaintiffs' complaints. Leaving aside the defendants' assertions regarding causation and damages until the parties have had a full opportunity to conduct discovery,[8] the Court will examine the parties' contentions *seriatim*.

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8. On February 14, 2000, the Court stayed all discovery unrelated to class issues until the parties' cross-motions for summary judgment were fully briefed and resolved. Since the parties have not conducted full discovery on the issues of causation and damages, those questions presently are not ripe for summary judgment.

Zenith protests that *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328 (1990), bars this tribunal from considering whether the defendants committed a *per se* violation of the Sherman Act until (Cont'd)

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1. Summary Judgment Standard

Summary judgment is appropriate when "the pleadings . . . show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Once the moving party demonstrates the absence of a genuine issue of material fact, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting FED. R. CIV. P. 56(e)). Accepting this evidence as truthful, the Court must view the record and all factual inferences therefrom in the light most favorable to the non-moving party and decide whether "'the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir. 1997) (quoting *Anderson*, 477 U.S. at 251-52).

2. The Sherman Antitrust Act and Illegality *Per Se*

Congress designed the Sherman Antitrust Act of 1890 as a "consumer welfare prescription" to protect free enterprise and competition. *Reiter v. Sonotone Corp.*, 442 U.S. 330,

(Cont'd)
the plaintiffs prove that they have suffered an "antitrust injury" under the Clayton Antitrust Act, 15 U.S.C. §§ 12- 37(a). As the Supreme Court observed in that case, however, "proof of a *per se* violation and of antitrust injury are distinct matters that must be shown independently." 495 U.S. at 344 (citation omitted). Accordingly, today's decision draws no conclusion regarding whether the plaintiffs have suffered an antitrust injury.

343 (1979) (citation omitted). Although section one of the Sherman Act literally bans every agreement "in restraint of trade," 15 U.S.C. § 1, this provision has been interpreted to prohibit only those contracts involving interstate commerce that "unreasonably" restrain competition. *Standard Oil Co. v. United States*, 221 U.S. 1, 55-60 (1911). Applying the "rule of reason," courts conduct an extensive and complex investigation into "the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption" to determine whether the challenged contract unreasonably restrains competition. *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 606 (1972) (citation omitted). Only blatantly anti-competitive agreements that predictably "tend to restrict competition and decrease output" may be condemned as unreasonable and illegal *per se* "without elaborate inquiry as to the precise harm they have caused or the business excuse for their use." *Broadcast Music, Inc. v. Columbia Broad. Sys.*, 441 U.S. 1, 19-20 (1979); *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (Black, J.).

3. The Challenged Accords are Illegal *Per Se*

"[W]hether the ultimate finding is the product of a presumption or actual market analysis, the essential inquiry remains the same—whether or not the challenged restraint enhances competition." *NCAA v. Board of Regents*, 468 U.S. 85, 103 (1984) (footnote omitted); *see also* 7 PHILLIP E. AREEDA, ANTITRUST LAW ¶ 1503a, at 372 (1986) ("Every antitrust suit should begin by identifying the ways in which a challenged restraint might possibly impair competition.").

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The defendants' agreements contain numerous covenants inimical to free enterprise.

In its agreement with Abbott, Geneva promised to withhold its FDA-approved capsule from the United States market, to refrain from selling its rights to that capsule and its tablet ANDAs, to oppose any attempts by other ANDA applicants to enter the market early, and, in the event that Geneva "successfully defended" its tablet ANDA before the Federal Circuit and secured a 180-day exclusivity period, to forgo marketing that tablet until Abbott exhausted any appeals before the Supreme Court. *See supra* pages 7-8. Similarly, in its accord with Abbott, Zenith agreed to dismiss its efforts to delist Abbott's Hytrin patents, to rebuff other entities' requests for help in challenging those patents, and, with the assurance of continued payment during any period of exclusivity enjoyed by a rival generic drug maker, to refrain from marketing the first generic terazosin hydrochloride product unless Abbott authorized Zenith to enter the market, or Abbott's patents elapsed. *See supra* pages 6-7.

Viewed together and in their factual context, these provisions illustrate that Geneva and Zenith forswore competing with Abbott in the United States market for terazosin hydrochloride drugs and promised to take steps to forestall others from entering that market for the life of their respective agreements in exchange for millions of dollars in monthly or quarterly payments. Geneva and Zenith were poised to compete with Abbott at the same level of the market; Geneva had received final FDA approval for its capsule pending validation and Zenith anticipated a favorable ruling that would result in final approval of its tablet proposal.

Prices were likely to fall as the output of terazosin hydrochloride drugs climbed. *See generally* 11 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1902a, at 191 (1998) ["HOVENKAMP"] (noting that horizontal agreements "enable participants to reduce the output of goods in some market, thus causing higher prices, inefficient substitutions, and the resultant losses in consumer welfare"). Instead of braving the rigors of competition, or unilaterally avoiding the arena, Geneva and Zenith both made pacts with Abbott to "enhance their collective profits to the detriment of consumers."[9] Abbott dissuaded Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period, eliminated the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim, and enlisted their potential cooperation in opposing or refusing to support other drug makers' ANDAs. This scheme of agreements clearly "den[ied] to consumers the opportunity to choose among alternative offers without offering the possibility of any joint, efficiency-producing activities." *See United States v. Realty Multi-List, Inc.*, 629 F.2d 1351, 1364 (5th Cir.1980) (citation omitted).[10] Under

9. 7 PHILLIP E. AREEDA, ANTITRUST LAW ¶ 1503a, at 374; *see Palmer v. BRG*, 498 U.S. 46, 49-50 (1990) (per curiam) (observing that plaintiff need not prove that defendants previously competed in relevant market to establish *per se* violation of 15 U.S.C. § 1); In re *Cardizem CD Antitrust Litig.*, 105 F. Supp.2d 618, 677-79 (E.D. Mich. 2000) ["*Cardizem I*"] (same). These agreements did not deprive Geneva or Zenith of the opportunity to sell terazosin hydrochloride drugs outside the United States.

10. In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981), the Court of Appeals for the Eleventh Circuit adopted as binding precedent all decisions that the former Court of Appeals for the Fifth Circuit rendered before October 1, 1981.

this scheme, the defendants would earn their profits by limiting marketwide output and maintaining a higher price for Abbott's product.

Abbott's agreements with Geneva and Zenith to forestall competition in the United States for sales of terazosin hydrochloride drugs confront the Court with "[o]ne of the classic examples of a *per se* violation"—"an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition " *Topco Assocs., Inc.*, 405 U.S. at 608.

> Such concerted action is usually termed a "horizontal" restraint, in contradistinction to combinations of persons at different levels of the market structure, *e.g.*, manufacturers and distributors, which are termed "vertical" restraints. This Court has reiterated time and time again that "[h]orizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition." Such limitations are *per se* violations of the Sherman Act.

Id. (citations omitted); *see also id.* at 613 (Burger, C.J., dissenting) (observing that *per se* rule rightly condemns horizontal agreements "involv[ing] restraints on interbrand competition or an allocation of markets by [an entity or group] with monopoly or near-monopoly control of the sources of supply"). *See generally* HOVENKAMP, *supra* page 11, ¶ 1902a, at 190 ("Horizontal agreements are antitrust's most 'suspect' classification.").

When presented with a plainly anti-competitive contract, the Court "need not then inquire whether the [defendants] actually possess the power to inflict public injury," or whether "the restraint . . . is justified by any procompetitive purpose or effect." *Realty Multi-List*, 629 F.2d at 1362. Nevertheless, this tribunal will examine the defendants' chief mitigating arguments, mindful that "[t]he probability that anticompetitive consequences will result from a practice . . . must be balanced against its pro-competitive consequences," *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 350 n.16 (1982), and that the defendants must "come forward with 'specific facts showing that there is a genuine issue for trial'" on the potential consequences of their accords. *See Matsushita Elec. Indus. Co.*, 475 U.S. at 587.

4. The Defenses Offered by Defendants are Invalid

The defendants claim immunity from the *per se* rule on several grounds. First, they contend that the challenged agreements tended to foster competition or had no impact on their ability to compete. Second, they argue that the agreements are beyond the scope of the *per se* rule because they were novel, analogous to patent settlements, or designed to influence government organizations. These arguments are not persuasive, and the defendants' evidence does not establish a genuine issue for trial.

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A. Economic Justifications for Challenged Accords

1. Pro-Competitive Motives or Provisions

The defendants maintain that their agreements would have tended to advance competition by ending or preventing fractious patent disputes and eliminating obstacles to Geneva and Zenith's entrance into the United States market for terazosin hydrochloride products. Of course, the Supreme Court "has consistently rejected the notion that naked restraints of trade are to be tolerated because they are well intended or because they are allegedly developed to increase competition." *Topco Assocs., Inc.*, 405 U.S. at 610 (citations omitted). Viewed in the light most favorable to the defendants, however, the record does not substantiate that the Geneva and Zenith Agreements were reasonably ancillary to pro-competitive activity rather than unreasonable restraints of trade.

The Geneva Agreement did not enhance competition. According to the defendants, Geneva contracted with Abbott to avoid "substantial legal and financial risks" accompanying the introduction of its capsule product, furthering "the public policy preference for deferring generic entry until after the resolution of any patent dispute with respect to any given drug." (Abbott Statement at 7 (citations omitted); *id.* at 13 (citing Decl. of Steven N. Wiggins, Econ. Professor, Texas A & M Univ., at ¶¶ 14-22, 32-48).) Accepting these allegations as true, it is readily apparent that Geneva did *not* have to enter into a contract with Abbott in order to defer its entry into the United States market.

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Abbott's confidential agreement with Geneva did not resolve its action before the Northern District of Illinois; in fact, it tended to prolong that dispute to Abbott's advantage. Geneva agreed to accept over a million dollars per week to refrain from marketing any generic terazosin hydrochloride product until another drug maker sold a generic version of Hytrin in the United States, or it received an unappealable judgment that its proposed generic tablet did not infringe Abbott's patents. (G.A. at 3-5.) The latter condition restrained Geneva from marketing its products during the pendency of any Supreme Court review, even if Geneva obtained a favorable ruling from the Federal Circuit in satisfaction of FDA's successful defense requirement. This design did not enhance competition.[11]

Geneva would have been able to market terazosin hydrochloride products in the United States without objection if Abbott elected to end its payments, (G.A. at 4), but this clause cannot justify the defendants' comprehensive and unreasonable restraints. One could reasonably infer that this clause was a catalyst for competition if Geneva paid Abbott for it, but the suggestion that Abbott handsomely paid Geneva to spur competition in its own lucrative domestic market for terazosin hydrochloride products is patently unreasonable.

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11. *See* 59 Fed. Reg. at 50,354 ("The likelihood of an appellate court decision being heard and overruled by the Supreme Court is too remote to warrant delaying marketing and exclusivity pending resolution of a petition for writ of certiorari."). Further, Geneva also promised to "join and support any motion filed by Abbott . . . in the Northern District of Illinois" seeking an extension of FDA's 30-month stay on approval of its proposed tablet, potentially delaying the proceedings even further. (G.A. at 5.)

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See In re *Cardizem CD Antitrust Litig.*, 105 F. Supp. 682, 699 (E.D. Mich. 2000) ["*Cardizem II*"] (concluding that drug makers' alleged agreement to allocate United States market for brand-name drug Cardizem CD provided "an incentive to stay off the market"); *Cardizem I*, 105 F. Supp.2d at 679 (noting that defendant "ignore[d] the reasonable inference that HMRI would not have paid Andrx millions of dollars to stay off the market beyond July 9, 1998, if it was not reasonably probable that Andrx would enter the market"). The Geneva Agreement clearly sought to curtail the domestic sale of generic terazosin hydrochloride drugs.

The Zenith Agreement also sought to restrain domestic competition. Zenith confidentially agreed to terminate its potentially meritorious challenge to Abbott's Hytrin patents in the District of New Jersey and the Federal Circuit in exchange for three million dollars. Thereafter, in a separate series of transactions, Zenith would receive millions of dollars to "not sell, offer for sale, donate, or otherwise commercially distribute in the United States any [t]erazosin [h]ydrochloride [p]roduct" until another drug maker sold a generic version of Hytrin in the United States, among other things. (Z.A. at 3.) Zenith also promised "not [to] aid or assist any person or entity to gain FDA approval to market a[t]erazosin [h]ydrochloride [p]roduct," but once generic competition began, Zenith could market such products in the United States without objection from Abbott. (*Id.* at 6.) The Zenith Agreement would indefinitely postpone Zenith's entry into the United States market and would permit competition only once Abbott lost its exclusive market. Like its agreement with Geneva, Abbott's agreement with Zenith resulted in a cooperative effort to forestall competition, not to enhance it.

2. Ineffective Restraints

Next, the defendants contend that their agreements could not unreasonably restrain the domestic market for terazosin hydrochloride products because Geneva was unable to validate its capsule product and legally enter the market until August, 1999, and Zenith was subject to Geneva's 180-day period of exclusivity on March 31, 1998. Although the Court accepts the defendants' allegations of fact as true for purposes of resolving the plaintiffs' motion for partial summary judgment, *Allen*, 121 F.3d at 646, the contention that Zenith could not enter the market in March, 1998, draws a legal conclusion and must be disregarded by the Court under FED. R. CIV. P. 56(e).[12] Indeed, the defendants' allegations are irrelevant, for it is well-settled that

> conspiracies under the Sherman Act are not dependent on any overt act other than the act of conspiring. It is the 'contract, combination . . . or conspiracy, in restraint of trade or commerce' which § 1 of the Act strikes down, *whether the concerted activity be wholly nascent or abortive on the one hand, or successful on the other.*

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12. (*E.g.*, Zenith Opp'n, Mar. 20, 2000, at 5 (drawing legal conclusion)); *see Beard v. Annis*, 730 F.2d 741, 743 (11th Cir.1984) (rejecting statements of law as inadmissible); 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2738, at 346-56 (1998). The defendants' legal allegation pointedly ignores FDA's November 5, 1997, pronouncement that the agency would continue to enforce the successful defense regulation. (*See* Walgreen Pls.' Reply to Zenith, Apr. 3, 2000, at 2.) That was the state of the law on March 31, 1998.

United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 224 n.59 (1940) (citations omitted and emphasis added); *see Maricopa County Med. Soc.*, 457 U.S. at 345 (following *Socony-Vacuum Oil Co.* decision); *see also* AMERICAN BAR ASS'N, ANTITRUST LAW DEVELOPMENTS 79 (4th ed.1997).

B. Similarity of Accords to Contracts Beyond the Scope of the *Per Se* Rule

Having failed to identify a genuine issue of fact concerning the anti- competitive potential of their agreements to allocate the United States market for terazosin hydrochloride products to Abbott, the defendants attempt to redraw their accords as novel compacts, patent settlements, or petitions not subject to the *per se* rule. These efforts are also unpersuasive.

1. Novel Agreements

Zenith, Geneva, and Abbott assert that the impact of their agreements "is not immediately obvious" because the judiciary lacks experience with "agreement[s] between brand[ed] and generic drug manufacturers . . . to settle novel delisting claims and patent litigation and [to] speed introduction of the generic . . . product into the market." (Zenith Opp'n at 12; *see* Geneva Opp'n, Mar. 21, 2000, at 8 ("[n]ot a single court has evaluated whether agreements such as these . . . are anticompetitive"); Abbott Opp'n, Mar. 20, 2000, at 20.) This assertion is incorrect. American courts have extensive experience with horizontal market allocation agreements and their foreseeable anti-competitive effects.

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Without belaboring the point, the undisputed record and the plain text of Abbott's agreements with Geneva and Zenith bespeak the defendants' intent to eliminate domestic competition for sales of terazosin hydrochloride products in the short run and delay the onset of generic competition. Such horizontal agreements to allocate territories remain illegal *per se* under section one of the Sherman Act even if they involve complex disputes involving pharmaceutical companies. *See Maricopa County Med. Soc.*, 457 U.S. at 349 (rejecting argument that Supreme Court "should not apply the *per se* rule in this case because the judiciary has little antitrust experience in the health care industry"); *Cardizem II*, 105 F. Supp.2d at 705-06 (declaring defendants' horizontal market allocation agreement illegal *per se*); *Cardizem I*, 105 F. Supp.2d at 676-77 (rejecting "novelty" arguments raised by drug makers HMRI and Andrx to dismiss consolidated Sherman Act challenges). Certainly, the *per se* rule must be "applied infrequently and with caution" to avoid "mislabeling procompetitive activity as *per se* illegal," *Seagood Trading Corp. v. Jerrico*, 924 F.2d 1555, 1567 (11th Cir. 1991), but the rule need not "be rejustified for every industry that has not been subject to significant antitrust litigation." *See Maricopa County Med. Soc.*, 457 U.S. at 350-51. The Sherman Act "establishes one uniform rule applicable to all industries alike." *Socony-Vacuum Oil Co.*, 310 U.S. at 222. Contrary to the defendants' assertions, this case does not involve "the 'mere attachment of a *per se* label . . . to defendants' conduct,'" or an attempt to "'throw labels . . . around loosely.'" (Zenith Opp'n at 13 (citation omitted).) The defendants' confidential and comprehensive allocation of the United States market for the sale of terazosin hydrochloride products should be denounced under the *per se* rule.

2. Patent Settlements

Zenith and Abbott claim that the challenged accords are analogous to patent settlement agreements and that the *per se* rule does not apply to such settlements. (Zenith Opp'n at 12; Abbott Opp'n at 26-27 ("antitrust cases considering settlements of patent . . . disputes are consistently evaluated under the rule of reason").) Again, the defendants are mistaken. Abbott's agreement with Geneva did not resolve its infringement suit in the Northern District of Illinois, and while Zenith agreed to dismiss its appeal before the Federal Circuit in exchange for three million dollars, this exchange was part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride products. Furthermore, the Supreme Court has reviewed patent settlements under the *per se* rule. *E.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 377 (1952). The *per se* rule applies to the defendants' conduct.

3. Efforts to Influence Government Action

Lastly, Abbott seeks the shelter of the *Noerr-Pennington* doctrine, which shields legitimate efforts to influence public officials from potential antitrust liability. (*See* Abbott Opp'n at 27-29) (citing *McGuire Oil Co. v. Mapco*, 958 F.2d 1552, 1560 (11th Cir. 1992).) *See generally California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127, 137-38 (1961). The *Noerr-Pennington* doctrine "protect[s] those acts reasonably and normally attendant upon effective litigation," including threats of suit, and demand letters, *Mapco*, 958 F.2d at 1560 (citation omitted), but does

not condone contracts bearing a "resemblance to the combinations normally held violative of the Sherman Act, [including] . . . market-division agreements." *Noerr Motor Freight*, 365 U.S. at 528; *see Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 507 (1988). Consequently, the challenged agreements are not entitled to refuge under this doctrine.

Abbott's confidential agreements with Geneva and Zenith were not legitimate efforts to influence public officials; rather, they implemented the defendants' scheme to restrain the domestic sale of generic terazosin hydrochloride products without government scrutiny. *Noerr-Pennington* immunity does not apply to restraints adopted by private entities; it extends only when "the alleged restraint of trade [is] the intended consequence of public action." *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 424-25 (1990). Further, clandestine restraints of trade are not "normally attendant upon" patent litigation. Contrary to Abbott's assertion, the Court of Appeals' *Mapco* decision does not "flatly contradict [that] position," or hold that price-fixing stipulations adopted by opposing parties in ongoing litigation are entitled to *Noerr-Pennington* immunity. *See Mapco*, 958 F.2d at 1561-62 (rejecting defendant's narrow argument that plaintiffs' "concerted threats [of suit] and institution of litigation . . . violated the Sherman Act"). Abbott's efforts to parlay its patents into agreements with its competitors to limit the domestic sale of generic terazosin hydrochloride drugs is exactly "the type of commercial activity that has traditionally had its validity determined by the antitrust laws." *Allied Tube & Conduit Corp.*, 486 U.S. at 505.

Appendix B

CONCLUSION

Both the Geneva Agreement and the Zenith Agreement warrant condemnation as *per se* violations of section one of the Sherman Antitrust Act. This tribunal's extensive review of the undisputed record has validated the presumption that the defendants' horizontal market allocation agreements would tend to inhibit domestic output and price competition without creating efficiencies for American consumers, and the defendants have not adduced sufficient facts to place the illegality of their restraints in genuine dispute. Therefore, for the reasons stated in the foregoing opinion, it is hereby

ORDERED that the Sherman Act Plaintiffs' motion for partial summary judgment [**D.E. No. 21, Civ. No. 99-MDL-1317**] is GRANTED, and it is

ORDERED that defendant Zenith Goldline Pharmaceuticals, Inc.'s motion for summary judgment [**D.E. No. 77, Civ. No. 98-3125; D.E. No. 45, Civ. No. 99-1938**] is DENIED without prejudice to its arguments regarding causation and damages, which may be renewed at the close of Phase II discovery.

DONE and ORDERED in Miami, Florida, this 13th day of December, 2000.

s/ Patricia A. Seitz
PATRICIA A. SEITZ
UNITED STATES DISTRICT JUDGE

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT DENYING PETITION FOR REHEARING EN BANC FILED NOVEMBER 18, 2003

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 02-12091-JJ

VALLEY DRUG COMPANY, LOUISIANA WHOLESALE DRUG CO., INC. ET AL.,

Plaintiffs-Appellees,

versus

GENEVA PHARMACEUTICALS, INC., ABBOTT LABORATORIES,

Defendants-Appellants.

On Appeal from the United States District Court for the Southern District of Florida

ON PETITION (S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

(Opinion _____ 11th Cir., 19__, __F.2d __).

Before: TJOFLAT and ANDERSON, Circuit Judges, and STAFFORD, District Judge.

Appendix C

PER CURIAM:

The Petition (s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

s/ RL Anderson
UNITED STATES CIRCUIT JUDGE

APPENDIX D — STATUTES INVOLVED

Section 1 of the Sherman Act

15 U.S.C. § 1. Trusts, etc., in restraint of trade illegal; penalty

> Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

21 U.S.C. § 355. New drugs

> (a) Necessity of effective approval of application
>
> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.
>
> * * *

Appendix D

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

* * *

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

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* * * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacturer, use, or sale of the new drug for which the application is submitted.

* * *

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject

of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

* * *

(5)

* * *

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

Appendix D

* * * *

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial

manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action.

* * * *

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

Appendix D

* * * *

35 U.S.C. § 271. Infringement of patent

* * *

(e)

* * *

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

* * *

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

* * *

(4) For an act of infringement described in paragraph (2)

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

* * * *

APPENDIX E — AGREEMENT

AGREEMENT

This Agreement ("Agreement") is made and entered into this 1st day of April, 1998, between Geneva Pharmaceuticals, Inc. and Abbott Laboratories.

WHEREAS, Geneva Pharmaceuticals, Inc. ("Geneva") has submitted an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Abbott Laboratories' ("Abbott's") HYTRIN® (terazosin hydrochloride) tablets, which has been designated as ANDA No. 74-315, and has submitted an ANDA to the FDA seeking approval to market a generic version of Abbott's HYTRIN® (terazosin hydrochloride) capsules, which has been designated as ANDA No. 74-823;

WHEREAS, Abbott is the owner of United States Patent No. 5,504,207 ("the '207 patent"), which claims, *inter alia,* Form IV anhydrous terazosin hydrochloride;

WHEREAS, Geneva has acknowledged that its proposed generic terazosin hydrochloride tablets and proposed generic terazosin hydrochloride capsules would infringe claim 4 of Abbott's '207 patent, if valid and enforceable;

WHEREAS, Abbott and Geneva acknowledge that an actual controversy exists between them concerning the validity and enforceability of the '207 patent, which is the subject of *Abbott Laboratories v Geneva Pharmaceuticals, Inc.,* Case No. 96 C 3331, pending in the United States District Court for the Northern District of Illinois;

Appendix E

WHEREAS, Geneva has recently obtained final FDA approval of its ANDA No. 74-823 for a generic terazosin hydrochloride capsule product; and

WHEREAS, the Parties desire to avoid the risk and expenses associated with emergency litigation with respect to the validity and enforceability of the '207 patent and its impact on Geneva's rights to market its proposed generic terazosin hydrochloride capsules;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement, Abbott and Geneva agree as follows:

Definitions

1. "Abbott" means Abbott Laboratories, as well as its Affiliates, successors in interest, and assigns.

2. "Geneva" means Geneva Pharmaceuticals, Inc. as well as its Affiliates, successors in interest, and assigns.

3. "Affiliate" of any Party means any entity which, directly or indirectly, owns or controls, is under common ownership or control with, or is owned or controlled by such Party.

4. "Party" or "Parties" means Geneva and/or Abbott as defined in Paragraphs 1 and 2 of this Agreement.

5. "Case No. 96 C 3331" means *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, now pending in the United States District Court for the Northern District of Illinois, and any appeal taken therefrom.

6. "FDA" means the United States Food and Drug Administration.

7. "Terazosin Hydrochloride Product" means any pharmaceutical product, regardless of formulation or dosage form (tablet, capsule, etc.), containing terazosin hydrochloride.

8. "The '207 patent" means Abbott's United States Patent No. 5,504,207.

9. "ANDA" means an abbreviated new drug application submitted to the FDA pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(j).

10. "Commercial Sale" means the introduction or delivery for introduction into commerce of a drug product approved by the FDA, but does not include transfer of the drug product for reasons other than sale or for investigational use under 21 C.F.R. Part 312.

11. "Generic Entry" means the first Commercial Sale in the United States by any person other than Geneva of a Terazosin Hydrochloride Product that was manufactured pursuant to an ANDA approved by the FDA.

12. "Generic Entry Date" means the earlier of (a) the first date on which either Party provides notice in good faith (including all facts or evidence of such Generic Entry known to the Party sending such notice), pursuant to Paragraph 32 of this Agreement, to the other Party of the occurrence of Generic Entry; or (b) the last of (i) the expiration date for

Abbott's United States Patent No. 4,251,532 or (ii) the expiration of any statutory exclusivity period provided to Abbott by law for Terazosin Hydrochloride Products.

13. "Final Judgment in Abbott's Favor" means the entry pursuant to Federal Rule of Civil Procedure 79(a) by the United States District Court for the Northern District of Illinois in Case No. 96 C 3331 of a final, appealable judgment that Geneva's Terazosin Hydrochloride Products infringe or would infringe any valid and enforceable claim of the '207 patent.

14. "Final Judgment in Geneva's Favor" means the entry pursuant to Federal Rule of Civil Procedure 79(a) by the United States District Court for the Northern District of Illinois in Case No. 96 C 3331 of a final, appealable judgment that Geneva's Terazosin Hydrochloride Products do not infringe or would not infringe any valid and enforceable claim of the '207 patent.

15. "Appellate Judgment" means (a) if neither Party timely files a notice of appeal from a Final Judgment, the first date after which the time for filing a notice of appeal under the Federal Rules of Appellate Procedure has expired; (b) if neither Party timely files a Petition for Writ of Certiorari, the date that a mandate issues from the United States Court of Appeals for the Federal Circuit on an appeal from a Final Judgment in Geneva's Favor or a Final Judgment in Abbott's favor, or (c) if either Party timely files a Petition for Writ of Certiorari in the United States Supreme Court, the date of the opinion or order of the Supreme Court disposing of the case; provided, however, that as to both

clauses (b) and (c) of this Paragraph, a remand to the District Court or to the United States Court of Appeals for the Federal Circuit for further substantive proceedings shall not constitute an Appellate Judgment.

Payments

16. On April 30, 1998, and thereafter on the fifth business day after the end of each calendar month beginning with May, 1998, Abbott shall pay to Geneva $4,500,000 by wire transfer pursuant to wire instructions provided by Geneva. Provided, however, that:

(a) Abbott shall not be obligated under any circumstances to pay any sums for any period of time after the Generic Entry Date and, as to the month in which the Generic Entry Date occurs, Abbott shall pay Geneva a prorated portion of the $4,500,000 for the time period in such month prior to the Generic Entry Date.

(b) Abbott shall not be obligated under any circumstances to pay any sums for any period of time after the date of a Final Judgment in Abbott's Favor, and as to the month in which the Final Judgment in Abbott's Favor occurs, Abbott shall pay Geneva a prorated portion of the $4,500,000 for the time period in such month prior to the date of the Final Judgment in Abbott's Favor.

(c) If a Final Judgment in Geneva's Favor is entered, Abbott shall pay to Geneva a prorated portion of

the $4,500,000 for the time period in such month prior to the date of the Final Judgment in Geneva's Favor. Thereafter, as to the remainder of the month in which the Final Judgment in Geneva's Favor is entered, Abbott shall pay into escrow a prorated portion of $4,500,000 for the time period in such month after the date of the Final Judgment in Geneva's Favor. The escrowed payments shall be held with an escrow agent, and pursuant to escrow arrangements, reasonably acceptable to both Parties. Escrowed payments at the rate of $4,500,000 per month shall continue until the earlier of the Generic Entry Date, the Appellate Judgment, or the date of a Final Judgment in Abbott's Favor.

(i) If the Appellate Judgment provides that Geneva's Terazosin Hydrochloride Products do not infringe or would not infringe any valid and enforceable claim of the '207 patent, Abbott shall take all steps necessary to release to Geneva any such escrowed amount, with interest, if any, no later than the fifth business day after the Appellate Judgment;

(ii) If the Appellate Judgment provides that Geneva's Terazosin Hydrochloride Products infringe or would infringe any valid and enforceable claim of the '207 patent, Geneva shall take all steps necessary to release to Abbott any such escrowed amount, with interest, if any, no later than the fifth business day after the Appellate Judgment; or

(iii) If, after monies have been paid into escrow pursuant to Paragraph 16(c), there is a Final Judgment in Abbott's Favor, then Geneva shall take all steps necessary to release to Abbott any such escrowed amount, with interest, if any, no later than the fifth business day after the Final Judgment in Abbott's Favor.

(d) If the Generic Entry Date has not occurred on or before February 18, 2000, Abbott shall have the option of terminating its payment obligations under this Paragraph 16 upon thirty (30) days' written notice to Geneva. If Abbott elects to terminate its payment obligations, Abbott shall provide Geneva with a covenant not to sue it for, patent infringement on Geneva's Terazosin Hydrochloride Product(s) under claim 4 of the '207 patent.

Other Covenants

17. Geneva affirms that (i) as of the date of this Agreement it is the owner of ANDA No. 74-315 for terazosin hydrochloride tablets, and ANDA No. 74-823 for terazosin hydrochloride capsules; (ii) that ANDA No. 74-823 and ANDA No. 74-315 are the only ANDAs Geneva has submitted for approval of any Terazosin Hydrochloride Product; (iii) that Geneva has not assigned or transferred, and shall not assign or transfer, its rights under either ANDA No. 74-315 or under ANDA No. 74-823 to any other entity; and (iv) that Geneva has obtained final marketing approval from the FDA for ANDA No. 74-823.

Appendix E

18. The Parties agree that a Final Judgment in Abbott's Favor, a Final Judgment in Geneva's Favor and/or an Appellate Judgment in Case No. 96 C 3331 apply with equal force and binding effect as to Geneva's rights under ANDA No. 74-823. The Parties agree to take any steps necessary to effectuate this Paragraph; provided, however, that Geneva is not agreeing hereby to consent to the amendment of the Complaint in Case No. 96 C 3331 to include a claim by Abbott that Geneva's terazosin hydrochloride capsules infringe the '207 patent.

19. Geneva agrees to join and support any motion filed by Abbott in Case No. 96 C 3331, Case No. 96 C 5868 and/or Case No. 97 C 7587, pending in the United States District Court for the Northern District of Illinois, which seeks an extension of any 30 month period provided by 21 U.S.C. § 355(j)(4)(B)(iii) up to and including the Appellate Judgment.

20. Except as permitted in Paragraph 16(d), Geneva shall not sell, offer for sale, donate, or otherwise distribute in the United States any Terazosin Hydrochloride Product until after the earlier of (1) the Generic Entry Date, or (2) the Appellate Judgment.

21. Geneva agrees to use its best efforts to oppose any attempts by any ANDA applicant that is a party to litigation involving terazosin hydrochloride patents to assert that it is entitled to approval of its ANDA for a Temzosin Hydrochloride Product prior to the date currently determined pursuant to 21 C.F.R § 314.107.

Appendix E

Confidentiality

22. The financial terms of this Agreement, including, but not limited to the terms of Paragraph 16 of this Agreement, shall remain confidential to the Parties, and shall not be disclosed to third parties; provided, however, that the disclosure of the financial terms of this Agreement shall not be considered a breach of this Agreement where ordered by a court in a legal proceeding, or otherwise required by law in the opinion of the Party's legal counsel. In such event, however, the Party disclosing the financial terms of this Agreement must (a) notify the other Party of the nature, content, and source of any request or demand for disclosure of such terms immediately upon receipt of such request or demand; (b) oppose a request or demand for disclosure of such information; (c) give 3 business days' prior written notice to the other Party of the nature and content of the disclosure and of the person(s) to whom such disclosure shall be made; and (d) reasonably consider any comments made by the other Party concerning the nature, content and extent of such disclosure.

Remedies and Dispute Resolution

23. Except as provided in Paragraph 24, the Parties agree that any dispute arising under this Agreement must be resolved in accordance with the Alternative Dispute Resolution ("ADR") procedures attached as Exhibit A. The Parties consent to the jurisdiction of the United States District Court for the Northern District of Illinois and agree that such court is the sole proper forum for any actions in enforcement of this Agreement.

24. In addition to any other rights or remedies Abbott may have for breach of this Agreement, Abbott specifically reserves the right to seek temporary, preliminary and permanent injunctive relief in the United States District Court for the Northern District of Illinois if Geneva breaches Paragraph 20 of this Agreement.

Other Provisions

25. The Parties understand that, subject to the provisions of this Agreement, Geneva intends to use its best efforts to obtain any statutory period of exclusive marketing to which it may be entitled under 21 U.S.C. § 355(j)(4)(B)(iv).

26. Each Party agrees that, at the request of the other, it will cooperate fully in seeking a stay of mandate pursuant to Federal Rule of Appellate Procedure 41(b) pending a Petition for Writ of Certiorari to the Supreme Court.

27. The Parties agree that this Agreement has been negotiated at arms length and between persons sophisticated and knowledgeable in the matters dealt with here. Each party has been represented by experienced and knowledgeable counsel. Accordingly, any rule of law or legal decision that would interpret ambiguities against the drafter is not applicable and is waived. The provisions of this Agreement shall be interpreted in a reasonable manner to effect the purpose of the Parties and this Agreement.

28. This Agreement and any exhibits attached hereto constitute the entire agreement between the Parties and supersede any prior understandings, agreements or

representations by and between the Parties regarding this Agreement, written or oral.

29. This Agreement may be amended only by a writing executed by each of the Parties.

30. This Agreement may be executed in counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same instrument.

31. The Parties agree that this Agreement shall be governed by the law of the State of Illinois, without regard to choice of law principles.

Notice

32. The Parties agree that any notice to be given pursuant to this Agreement shall be made by telecopy and, on that same day, by overnight courier service upon the following individuals:

To Abbott:

President
Pharmaceutical Products Division
Dep't 309, Bldg. AP30
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-3537
Telecopy: 847/938-5383

with a copy to: General Counsel
Legal Division
Dep't 364, Bldg. AP6D
Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064-3500
Telecopy: 847/938-6277

To Geneva: President
Geneva Pharmaceuticals, Inc.
2655 W Midway Boulevard
Broomfield, Colorado 80038
Telecopy: 303/466-6378

Notice is effective upon a receipt by the sender of a confirmation from the sender's telecopier of sending the telecopy to the attention of the above-identified individuals.

This Agreement has been duly executed and delivered by an authorized representative of each of the following Parties and will be valid and binding against each of them.

DATE: April 7, 1998 **GENEVA PHARMACEUTICALS, INC.**

AGREED TO AND ACCEPTED

By: s/ [illegible]
Title: [illegible]

Appendix E

DATE: April 1, 1998 **ABBOTT LABORATORIES**

AGREED TO AND ACCEPTED

By: s/ [illegible]
Title: President, Pharmaceutical Products Division

APPENDIX F — SETTLEMENT AGREEMENT

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made and entered into this 31 day of March, 1998 by and among Zenith Laboratories, Inc., Zenith Goldline Pharmaceuticals, Inc., IVAX Corporation and Abbott Laboratories.

WHEREAS, Zenith Laboratories, Inc. and Abbott Laboratories are parties to *Zenith Laboratories, Inc. v. Abbott Laboratories,* Civil Action No. 96 Civ. 1661, pending in the United States District Court for the District of New Jersey ("the Civil Action") and Appeal No. 98-1026, pending in the United States Court of Appeals for the Federal Circuit ("the Appeal");

WHEREAS, Zenith and Abbott desire to avoid the risks and expenses associated with litigation and to settle the Civil Action and the Appeal amicably as set forth in this Agreement, without either Party admitting any liability to the other Party;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement, Zenith and Abbott agree as follows:

Definitions

1. "Zenith" means Zenith Laboratories, Inc., a Florida corporation, Zenith Goldline Pharmaceuticals, Inc., and IVAX Corporation and all of their respective subsidiaries, affiliates, successors in interest, and assigns.

Appendix F

2. "Abbott" means Abbott Laboratories, an Illinois corporation, as well as its subsidiaries, affiliates, successors in interest, and assigns.

3. "Party" or "Parties" means Zenith and/or Abbott as defined in Paragraphs 1 and 2 of this Agreement.

4. "FDA" means the United States Food and Drug Administration.

5. "ANDA" means an abbreviated new drug application submitted to the FDA pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(j).

6. "Commercial Sale" means the introduction or delivery for introduction into commerce of a drug product approved by the FDA, but does not include transfer of the drug product for reasons other than sale or for investigational use under 21 C.F.R. Part 312.

7. "Generic Terazosin Hydrochloride Product" means an FDA approved Terazosin Hydrochloride Product, excluding Abbott's branded Terazosin Hydrochloride Products sold and/or marketed under the HYTRIN® trademark.

7(a). "Generic Entry" means the first Commercial Sale in the United States by any person or entity including Abbott, but excluding Zenith, of a Generic Terazosin Hydrochloride Product.

8. "Generic Entry Date" means the earlier of 1) the date of Generic Entry; or 2) the last of (a) the expiration date for

Abbott's U.S. Patent No. 4,251,532 (the "532 Patent") (which currently is due to expire on February 17, 2000); or (b) the expiration of any statutory exclusivity period provided to Abbott by law for Terazosin Hydrochloride Products.

9. "Generic Exclusivity Period" means that period of time, not to exceed one hundred eighty (180) days, during which Zenith can sell no Terazosin Hydrochloride Product because the FDA has not granted to Zenith final marketing approval solely because of the provisions of 21 U.S.C. § 355(j)(4)(B)(iv).

10. "Terazosin Hydrochloride Product" means any pharmaceutical product, regardless of formulation or dosage form (tablet, capsule, etc.), containing terazosin hydrochloride.

11. "Abbott's Terazosin Hydrochloride Patents" means (1) U.S. Patent Nos. 4,251,532, 5,212,176, 5,268,182, 5,294,615, 5,362,730, 5,412,095, and/or 5,504,207, and any later reissues or reexaminations of any such patents; (2) any patent issued to Abbott by the United States Patent and Trademark Office from a patent application pending as of the date of execution of this Agreement, which specifically claims any process for making terazosin hydrochloride, or any form, any use, or any formulation, of terazosin hydrochloride; or 3) any other U.S. patent currently or hereafter owned by, assigned to, licensed by, or asserted by Abbott that would be infringed by the manufacture, use, sale or importation of any Terazosin Hydrochloride Product currently the subject of commercial sales or the subject of Zenith's current ANDA #74-530.

12. "Payment Period" means one of the payment periods described in Paragraph 16(a) of this Agreement.

13. "Orange Book" means the FDA publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations.*

Dismissal of Actions

14. Concurrently with the execution of this Agreement, the Parties shall execute and immediately file a Stipulation of Dismissal With Prejudice, in the form attached as Exhibit A to this Agreement, which dismisses the Civil Action with prejudice and provides that each party shall bear its own costs and attorneys' fees. The Parties shall take all other appropriate and reasonable actions necessary to ensure that this Stipulation is effectuated as soon as possible.

15. Concurrently with the execution of this Agreement, the Parties shall execute and immediately file a Stipulation of Dismissal of Appeal, in the form attached as Exhibit B to this Agreement, which dismisses the Appeal with prejudice as moot, and provides that each party shall bear its own costs and attorneys' fees. The Parties shall take all other appropriate and reasonable actions necessary to ensure that the Stipulation is effectuated as soon as possible and that any orders or opinions on the merits issued by the United States Court of Appeals for the Federal Circuit after March 23, 1998 be vacated and withdrawn as moot; provided, however, that the failure or refusal of the Court of Appeals to vacate or withdraw any such order or opinion shall not excuse the Parties' performance under this Agreement.

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Payments

16. Abbott shall pay Zenith the sum of $3,000,000 within one (1) business day after the filing of the Stipulations of Dismissal in the Civil Action and the Appeal. Such payment shall be non-refundable and shall not be subject to reduction or proration; provided, however, that if for any reason the District Court fails or refuses to dismiss the Civil Action with prejudice, then this Agreement shall terminate and become null and void, and any monies paid by Abbott to Zenith hereunder shall be immediately returned, and the Parties shall be deemed to have reverted to their respective status prior to the execution of this Agreement and shall proceed in all respects as if this Agreement had not been entered into, preserving in that event all of their respective claims and defenses in the Civil Action and the Appeal. Thereafter, assuming that the District Court has dismissed the Civil Action with prejudice, Abbott's payment obligations to Zenith shall be as follows:

(a) Abbott shall make payments to Zenith on the Payment Date as set forth in Table I for each full Payment Period that ends prior to the Generic Entry Date:

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TABLE I

Payment Period	Payment Date	Payment Amount (U.S. Dollars)
4/1/98 - 6/30/98	7/15/98	$3,000,000.00
6/31/98 - 9/30/98	10/15/98	$6,000,000.00
10/1/98 - 12/31/98	1/15/99	$6,000,000.00
1/1/99 - 3/31/99	4/15/99	$6,000,000.00
4/1/99 - 6/30/99	7/15/99	$6,000,000.00
7/1/99 - 9/30/99	10/15/99	$6,000,000.00
10/1/99 - 12/31/99	11/5/00	$6,000,000.00
1/1/00 - 2/17/00	3/1/00	$3,164,835.00

Abbott shall not be obligated to make the payments specified in Table I for the Payment Period in which the Generic Entry Date occurs or for any subsequent Payment Periods. Instead, Abbott shall be obligated only to make those payments required by Paragraphs 16(b) and (c) of this Agreement.

If the Generic Entry Date has not occurred on or before February 18, 2000, then Abbott shall not make the payment corresponding to the March 1, 2000 Payment Date above, and shall instead (if the Generic Entry Date has not occurred by March 31, 2000) make payment to Zenith of $6 million on April 15, 2000. If the Generic Entry Date occurs after February 18, 2000 but before April 1, 2000, then the payment required shall be calculated in accordance with Paragraph 16(b). For purposes of

this Agreement, April 15, 2000 shall be deemed a Payment Date, and the $6 million shall be deemed a Payment Amount. The Payment Period shall be from 1/1/00 to 3/31/00.

(b) With respect to the Payment Period, if any, in which the Generic Entry Date occurs, Abbott shall pay Zenith, on the Payment Date for such Payment Period, a prorated amount for that portion of the Payment Period that ended prior to the Generic Entry Date. Such prorated payment shall be calculated in accordance with the following formula:

$$\frac{\text{(number of days in Payment Period prior to the Generic Entry Date)}}{\text{(total number of days in such Payment Period)}} \times \text{(Payment Amount for such Payment Period)}$$

(c) If no Generic Exclusivity Period occurs, Abbott shall have no further payment obligation to Zenith after the Generic Entry Date. If a Generic Exclusivity Period occurs, then Abbott shall pay to Zenith, on the Payment Date(s) specified in Paragraph 16(a), a prorated amount for the duration of the Generic Exclusivity Period, calculated in accordance with the following formula:

$$\frac{\text{(number of days in Payment Period on and after the Generic Entry Date but during the Generic Exclusivity Period)}}{\text{(total number of days in such Payment Period)}} \times \text{(1/2 of the Payment Amount for such Payment Period)}$$

(d) Abbott shall have no obligation to pay Zenith any sums relating to any Payment Period after the expiration of the Generic Exclusivity Period, regardless of whether the FDA further delays or withholds the approval of Zenith's ANDA(s) for a Terazosin Hydrochloride Product.

(e) If the Generic Entry Date has not occurred on or before March 31, 2000 (thereby obligating Abbott to pay Zenith $6 million on April 15, 2000 pursuant to Paragraph 16(a)), Abbott shall have the option (on a calendar quarter by calendar quarter basis) of (i) continuing to pay Zenith the amount of $6 million per calendar quarter thereafter until the Generic Entry Date occurs, or (ii) allowing Zenith to enter the market as if Generic Entry Date had occurred. Abbott shall be deemed to have elected option (i) unless Abbott gives Zenith notice thirty (30) days prior to the start of the calendar quarter that Abbott has elected option (ii). If Abbott has elected option (i) Abbott shall make the required payment to Zenith and Zenith shall refrain from selling a Terazosin Hydrochloride Product until the Generic Entry Date occurs. Any such payment shall be made on the 15th day of the month following the end of each calendar quarter. If the Generic Entry Date occurs during the middle of any such calendar quarter, the payment shall be prorated in accordance with the following formula:

$$\frac{\text{(number of days in calendar quarter prior to the Generic Entry Date)}}{\text{(total number of days in such calendar quarter)}} \times \text{(\$6 million)}$$

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Covenants

17. Except as permitted in Paragraph 16(e), Zenith shall not sell, offer for sale, donate, or otherwise commercially distribute in the United States any Terazosin Hydrochloride Product until the Generic Entry Date.

18. In the event that the Generic Entry Date occurs prior to the expiration date of the '532 Patent, and thereafter all generic competitors, other than Zenith, who have commenced commercial sale of Terazosin Hydrochloride Products cease selling all such products in the United States due to legal action brought by Abbott enforcing any Abbott Terazosin Hydrochloride Patent, such that there is no generic competition to Abbott's branded Terazosin Hydrochloride Products other than Zenith, the following shall apply:

(i) Abbott shall notify Zenith of the occurrence of the foregoing events, including the commencement of any legal action described above and shall keep Zenith reasonably apprised of the progress of such proceedings, and Abbott shall cease selling, on or before the date following 3 business days of the sending of notice to Zenith of the withdrawal from the market of all generic competitors, any generic Terazosin Hydrochloride Product that it has launched;

(ii) On the date following 3 business days after receipt of notice from Abbott of the withdrawal from the market of all generic competitors, Zenith shall not sell, offer for sale, donate or otherwise commercially distribute in the United States any Terazosin Hydrochloride Product until the reoccurrence of a Generic Entry Date.

(iii) Abbott shall reinstitute the payments required by Paragraph 16 of this Agreement, which shall be prorated to cover only the period during which Zenith does not sell any Terazosin Hydrochloride Product; and

(iv) upon the reoccurrence of a Generic Entry Date, the Parties shall treat such further Generic Entry Date as triggering all of the respective rights and obligations under this Agreement which were triggered as of the original Generic Entry Date.

19. Zenith and Abbott mutually covenant to provide notice to the other in the manner provided in Paragraph 35 of their respective first Commercial Sale[s] of any Generic Terazosin Hydrochloride Product. Such notice shall be given no later than the end of the business day on the date of such first Commercial Sale.

20. Excluding any action for breach of this Agreement, Zenith covenants to refrain from taking any action or assisting any other person or entity in taking action, against Abbott with respect to Abbott's Terazosin Hydrochloride Patents including but not limited to (a) any interference or other proceeding before the United States Patent & Trademark Office; (b) any cause of action relating to non-infringement, invalidity, or unenforceability of any of Abbott's Terazosin Hydrochloride Patents, or regarding the propriety of their listing in the Orange Book; (c) any cause of action based upon an act or omission of Abbott up until the date of this Agreement relating to Zenith's entry into the market with a Terazosin Hydrochloride Product; and (d) any other action, including but not limited to tort actions, relating to Abbott's use, assertion or enforcement of its Terazosin Hydrochloride Patents.

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21. Excluding any action for breach of this Agreement, Abbott covenants to refrain from taking any action, or assisting any other person or entity in taking any action, before or against the FDA or any other legal or regulatory body with respect to any Zenith ANDA that seeks to market a formulation of a Terazosin Hydrochloride Product currently approved under any Abbott NDA ("Zenith ANDA") which intends to delay or prevent, or which delays or prevents, the approval of any Zenith ANDA. Also excluding any action for breach of this Agreement, Abbott further covenants that as of the date that Zenith is permitted under the terms of this Agreement to manufacture, have manufactured, market, use, import or sell Terazosin Hydrochloride Products (a) Abbott will refrain from claiming, orally or in writing, or through legal action or proceeding, that Zenith's manufacture, marketing, use, or sale of a Terazosin Hydrochloride Product which is the subject of any Zenith ANDA, or the importation of terazosin hydrochloride for use in the manufacture of a Terazosin Hydrochloride Product under any Zenith ANDA, infringes Abbott's Terazosin Hydrochloride Patents; (b) Abbott will refrain from asserting a claim for patent infringement or contributory patent infringement of Abbott's Terazosin Hydrochloride Patents against Zenith's customers arising from such customers' purchase or resale of Zenith's Terazosin Hydrochloride Product; and (c) to the extent that Abbott obtains a judgment of patent infringement against any supplier of terazosin hydrochloride, Abbott will refrain from enforcing such judgment with respect to that supplier's use, manufacture and sale of terazosin hydrochloride for use in Zenith's manufacture of a Terazosin Hydrochloride Product.

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22. Simultaneously with the execution of this Agreement, the Parties shall execute the Covenant Not To Sue attached hereto as Exhibit C. In the event that Abbott's obligations under Paragraph 21 of this Agreement are relieved for any reason, Abbott's obligations under this Covenant Not to Sue are similarly relieved.

23. Zenith recognizes and acknowledges the validity and enforceability of each of Abbott's Terazosin Hydrochloride Patents, and of each and every claim contained therein. Zenith further acknowledges that any potential Terazosin Hydrochloride Product it would market would infringe at least one of Abbott's Terazosin Hydrochloride Patents. Abbott agrees not to introduce into evidence Zenith's recognition and acknowledgment of the validity and enforceability and infringement of Abbott's Terazosin Hydrochloride Patents set forth in this Paragraph in defense against a claim of invalidity or unenforceability of any of Abbott's Terazosin Hydrochloride Patents and shall not otherwise introduce into evidence, assert or use offensively or defensively in any way this recognition and acknowledgment against any of Zenith's raw material suppliers, including specifically Byron Chemical Company or Uetikon, provided, however, that Abbott may assert this recognition and acknowledgment as a defense to a claim arising in any way out of or as a result of this Agreement. Furthermore, this recognition and acknowledgment shall not be binding on any person or entity other than Zenith, and specifically shall not be binding on any of Zenith's raw material suppliers, including Byron Chemical Company or Uetikon.

24. Zenith confirms that as of the date of this Agreement it is the owner of ANDA No. 74-530, for a Terazosin Hydrochloride Product, and that it has not assigned or transferred, and shall not assign or transfer, its rights under ANDA No. 74-530, or any other ANDA related to a Terazosin Hydrochloride Product, to any other entity other than one of its corporate affiliates, provided that Zenith shall guarantee such affiliate's performance of this Agreement. Additionally, and notwithstanding anything in this Agreement to the contrary, Zenith may assign ANDA No. 74-530 (and its rights thereunder), together with its rights and obligations under this Agreement, in connection with any sale of all or substantially all of its business. Zenith agrees that it shall promptly furnish to Abbott a copy of any letter to Zenith from the FDA granting approval (including tentative approval) of any ANDA for a Terazosin Hydrochloride Product.

25. Zenith agrees that it shall not aid or assist any other person or entity to gain FDA approval to market a Terazosin Hydrochloride Product; provided, however, that nothing in this paragraph or Agreement shall prohibit Zenith from complying with any lawfully issued subpoena or other discovery request. In the event that Zenith is served with a subpoena or discovery request which calls for the production or disclosure of materials or information which have been produced by Abbott to Zenith in the Civil Action and which have been designated "Confidential" or "Confidential-Attorney's Eyes Only" by Abbott pursuant to the Protective Order entered in the Civil Action, then Zenith will provide Abbott notice of such subpoena or discovery request prior to complying therewith.

26. Abbott affirms that U.S. Patent Nos. 4,251,532, 5,212,176, 5,268,182, 5,294,615, 5,362,730, 5,412,095, and 5,504,207 are all the United States patents issued to or owned by Abbott that specifically claim any process for making, any form, any use, or any formulation, of terazosin hydrochloride.

Releases

27. Except for the rights and obligations set forth in this Agreement, Zenith releases and forever discharges Abbott and its shareholders, directors, officers, employees, and attorneys, from any and all claims, demands, damages, actions, causes of action or liability of any kind or nature whatsoever, known or unknown, asserted or unasserted, existing or contingent, direct or derivative, that may now exist or which may hereafter be acquired, relating to any acts or omissions by Abbott in the United States up until the date of execution of this Agreement, which relate in any way to terazosin hydrochloride, including but not limited to any claim that Abbott improperly submitted any of its Terazosin Hydrochloride Patents for listing in FDA's Orange Book, that Abbott acted improperly in obtaining or enforcing any of its Terazosin Hydrochloride Patents, or any claims or causes of action that were or could have been raised in the Civil Action or the Appeal.

28. Except for the rights and obligations set forth in this Agreement, Abbott releases and forever discharges Zenith and its shareholders, directors, officers, employees and attorneys, from any and all claims, demands, damages, actions, causes of action or liability of any kind or nature

whatsoever, known or unknown, asserted or unasserted, existing or contingent, direct or derivative, that may now exist or which may hereafter be acquired, relating to any acts or omissions by Zenith in the United States up until the date of execution of this Agreement, which relate in any way to terazosin hydrochloride, including but not limited to any claims or causes of action that were or could have been raised in the Civil Action or the Appeal.

Press Releases

29. The Parties agree that if either of them intends to issue a written press release concerning or describing this Agreement, then with respect to any such press release, the party intending to issue such release shall provide the other party with an advance text of such release at least one (1) full business day prior to its issuance. The text of the press release shall be provided in the manner provided in Paragraph 35. This advance text shall be provided for information purposes only, and the party receiving such advance text shall have no right, authority or power to change or revise the content or the wording of the release. The party providing advance notice of such release shall be permitted to redact all portions of such release which do not relate to this Agreement. The party receiving an advance copy of any such release agrees to maintain the draft release and all information contained therein in strict confidence until such time as the release is issued publicly. This paragraph shall not apply to any public statements other than in the form of a press release.

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Other Provisions

30. **No Construction Against Drafter.** The Parties agree that this Agreement has been negotiated at arms length and between persons sophisticated and knowledgeable in the matters dealt with here. Each party has been represented by experienced and knowledgeable counsel. Accordingly, any rule of law or legal decision that would interpret ambiguities against the drafter is not applicable and is waived. The provisions of this Agreement shall be interpreted in a reasonable manner to effect the purpose of the Parties and this Agreement.

31. **Entire Agreement.** This Agreement and the exhibits attached hereto constitutes the entire agreement between the Parties regarding settlement of the Civil Action and the Appeal and supersedes any prior understandings, agreements or representations by and between the Parties regarding this settlement, written or oral.

32. **Amendments.** This Agreement may be amended only by a writing executed by each of the Parties.

33. **Miscellaneous.** This Agreement shall be binding upon and shall inure to the benefit of the Parties' respective successors and assigns. All payments under this Agreement shall be made by wire transfer to an account designated by Zenith.

34. **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same instrument.

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35. **Notice.** The Parties agree that any notice to be given pursuant to this Agreement shall be made by telecopy and, on that same day, by overnight courier service upon the following individuals:

To Abbott:
President
Pharmaceutical Products Division
Dep't 309, Bldg. AP30
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-3537
Telecopy: (847) 938-5383

with a copy to:
General Counsel
Legal Division
Dep't 364, Bldg. AP6D
Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064-3500
Telecopy: (847) 938-6277

To Zenith:
President
Zenith Goldline Pharmaceuticals, Inc.
4400 Biscayne Boulevard
Miami, Florida 33137-3212
Telecopy: (305) 575-4105

with a copy to:
General Counsel
IVAX Corporation
4400 Biscayne Boulevard
Miami, Florida 33137-3212
Telecopy: (305) 575-4105

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Notice is effective upon receipt by the sender of a confirmation from the sender's telecopier of a sending of the telecopy to the attention of the above-identified individuals.

36. A prevailing party shall be entitled to any reasonable attorneys' fees and court costs incurred in enforcing this Agreement or in defending any action brought in violation hereof.

This Agreement has been duly executed and delivered by an authorized representative of each of the following Parties and will be valid and binding against each of them.

DATE: March 31, 1998 **ZENITH LABORATORIES, INC. AGREED TO AND ACCEPTED**

By: s/ Rafick G. Henein
Rafick G. Henein
Title: President

DATE: March 31, 1998 **ZENITH GOLDLINE PHARMACEUTICALS, INC.**

AGREED TO AND ACCEPTED

By: s/ Rafick G. Henein
Rafick G. Henein
Title: President and Chief Executive Officer

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DATE: March 31, 1998 **IVAX CORPORATION**

AGREED TO AND ACCEPTED

By: s/ David R. Bethune
David R. Bethune
Title: President and Chief
Operating Officer

DATE: March 31, 1998 **ABBOTT LABORATORIES**

AGREED TO AND ACCEPTED

By: s/ Arthur Higgins
Title: President
Pharmaceutical Products Division